Supreme Court, U.S.
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In the Supreme Court of the United States

MERCK & CO., INC.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Federal Circuit is correct in holding that, because the *ultimate* issue of patent claim construction is one of law for the court under *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996), even the factual aspects of a district court's claim construction may be reviewed *de novo* on appeal.

2. Whether the Federal Circuit violated Fed. R. Civ. P. 52 and contravened precedents such as *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985), by rejecting admittedly plausible factual findings and credibility determinations supporting the district court's ultimate legal conclusion that the invention disclosed by petitioner's patent was not obvious.

3. Whether a patentee's strong showing of commercial success with a demonstrated nexus to an improvement invention covered by a patent can be disregarded as an indicator of the non-obviousness of the improvement because the patentee had exclusivity under earlier related patents.

RULE 14.1(b) AND 29.6 STATEMENT

Pursuant to Supreme Court Rule 14.1(b), petitioner Merck & Co., Inc. (Merck) states that all parties to the proceedings below appear in the caption of the case on the cover page. For clarity and to avoid any possible confusion, petitioner also notes that it is a completely separate legal entity from the unrelated German corporation that was the petitioner in this Court's recent decision in *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237 (June 13, 2005).

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent company and that there is no publicly held company that owns 10% or more of petitioner's corporate stock.

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OPINIONS BELOW

The majority and dissenting opinions of the court of appeals (App., *infra*, 1a-34a) are reported at 395 F.3d 1364. The opinion of the district court (App., *infra*, 43a-99a) is reported at 288 F. Supp. 2d 601. The order denying rehearing en banc and the dissenting opinion of three judges (App., *infra*, 35a-39a) are reported at 405 F.3d 1338.

JURISDICTION

The jurisdiction of the district court was invoked under 28 U.S.C. § 1338(a). The jurisdiction of the court of appeals was invoked under 28 U.S.C. § 1292(a)(1) and § 1295(a)(1). The court of appeals issued its judgment on January 28, 2005, and denied Merck's timely petition for rehearing on April 21, 2005. App., *infra*, 1a, 35a-39a. On June 23, 2005, Chief Justice Rehnquist extended the time within which to petition for a writ of certiorari to and including August 19, 2005. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION AND RULE INVOLVED

The statutory provision at issue is 35 U.S.C. § 103(a), entitled "Conditions for patentability; non-obvious subject matter," which provides:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rule at issue is Federal Rule of Civil Procedure 52(a), which provides:

> In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. * * *

STATEMENT

The FOSAMAX® medication developed by Merck was the first effective drug treatment for osteoporosis. Osteoporosis is a potentially debilitating disease afflicting millions, primarily post-menopausal women. It is caused by an imbalance in the body's natural process of destroying (or "resorbing") old bone and laying down new bone in its place. As people age, bone is resorbed faster than it is replaced. When the imbalance is too great, it can result in bones that are porous, brittle, and prone to fracture, leading to chronic pain, disability, and even death. Before the FDA approved Merck's daily FOSAMAX® products, post-menopausal women had only diet, exercise, and less satisfactory hormonal treatments to use against that serious disease.

This is the second patent infringement case related to FOSAMAX® between Merck and respondent Teva Pharmaceuticals USA, Inc. (Teva), a manufacturer of generic drugs.[1] The first case involved Merck's earlier '077 patent, which pioneered using the particular bisphosphonate in FOSAMAX®

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[1] Both cases were brought under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585 (also known as the "Hatch-Waxman Act").

(called "alendronate"), to treat osteoporosis, administered by "daily" dosing with 10-mg tablets (and then 5-mg tablets for prevention). See *Merck & Co., Inc.* v. *Teva Pharm. USA, Inc.*, 347 F.3d 1367 (Fed. Cir. 2003). In that case, the district court found infringement and upheld the validity and the patent term restoration of the '077 patent, and the Federal Circuit affirmed. *Id.* at 1369-74. Because Teva's challenge to Merck's '077 patent failed in the "daily" case, Teva is foreclosed from introducing generic alendronate tablets until after expiration of that patent and the related marketing exclusivity periods in February 2008. See 21 U.S.C. § 355(c)(2)(b).

The present patent infringement case involves Merck's '329 patent entitled "Method for Inhibiting Bone Resorption," in which the two claims at issue are directed to methods for treating or preventing osteoporosis through "once-weekly" administration of high alendronate doses. The parties have agreed that, when rewritten in independent form, the asserted claims read as follows (emphasis added):

> 23. A method for treating osteoporosis in a human comprising orally administering *about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis*, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.
>
> 37. A method for preventing osteoporosis in a human comprising orally administering *about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis*, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

The first question presented to this Court is squarely framed by the Federal Circuit's use of *de novo* review to disagree with the district court's construction of the highlighted phrases in claims 23 and 37 above.[2] The second and third questions chal-

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[2] As it did below, Merck refers to the "about 70 mg" and the "about 35 mg" phrases as shorthand for the entire disputed phrases, which appear in italics above.

lenge the Federal Circuit's increasing practice – in direct contradiction to this Court's cases – of reweighing a district court's detailed, plausible, and supported factual findings (in this case, as required by *Graham* v. *John Deere Co.*, 383 U.S. 1 (1966)), en route to reversing the district court's ultimate legal conclusion reached after a bench trial.

The FDA approved Merck's once-weekly FOSAMAX® dosing regimen in late 2000, and Merck began selling once-weekly tablets in November 2000. C.A. App. 718-19. Although Merck's 10- and 5-mg "daily" products were successful and enjoyed sales increases averaging more than $150 million each year before the once-weekly FOSAMAX® products were commercialized, the annual sales increases more than doubled after the improved once-weekly FOSAMAX® dosing regimen was introduced. C.A. App. 812-14, 817, 4007, 4006, 4340, 4344. That dramatic increase in physician and patient acceptance demonstrates that the invention created significant additional sales for the FOSAMAX® franchise.

A. State Of The Art in 1997: Widespread Belief That Alendronate Caused Dose-Related Side Effects

FDA approval for marketing FOSAMAX® as a high-dose, once-weekly tablet, as disclosed in the '329 patent, required Merck to undertake extensive clinical testing in support of a supplemental New Drug Application. 21 U.S.C. § 355(b); C.A. App. 527-28. The motivation for a weekly tablet was to avoid the inconvenient daily dosing regimen.[3] However, the '329 patent specification and the clinical studies it cited reflected the true state of the art at that time: strong apprehension over poten-

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[3] The dosing regimen for ingesting alendronate tablets required osteoporotic patients to take the tablets on an empty stomach with a full glass of water and to remain upright without eating for up to an hour after ingestion so as to avoid a broad spectrum of food substances that could destroy effectiveness and to avoid any prolonged contact of alendronate with the esophagus. C.A. App. 220-22, 600, 3786, 3832, 3951-52.

tial adverse side effects from oral administration of bisphosphonates at high doses.

After Merck's 10-mg daily FOSAMAX® tablets became publicly available, reports began surfacing of severe upper gastrointestinal injuries among osteoporotic patients. See, *e.g.*, C.A. App. 341-52, 3825-36. Ten articles detailing case reports of severe upper gastrointestinal injuries were published in peer-reviewed medical journals. C.A. App. 344-50, 354-56, 525-26, 3825-36, 3840-43, 3855-56, 3870-71. The report in the October 1996 *New England Journal of Medicine* was perhaps the most compelling for physicians. *Id.* at 348-51, 550-51, 3828-33, 4323. The lead author concluded that "alendronate can cause chemical esophagitis, including severe ulcerations in some patients." *Id.* at 3828-29, 3832, 348-52. In response, Merck notified the FDA and warned physicians of the potential for upper gastrointestinal injury from daily FOSAMAX® tablets, urging strict adherence to the dosing instructions. *Id.* at 615-16, 631-32, 664, 3782-84. Because such side effects were reported as dose-related, any suggestion to increase the dose would have directly contradicted accepted clinical experience. Among those who adopted and publicly advocated avoiding gastric injury by administering the bisphosphonates in smaller doses more often each day was Teva's bone and bisphosphonate expert in this case, Dr. Russell. C.A. App. 580.

The concern in the art about alendronate deterred any escalation to higher unit doses. C.A. App. 348-49. Merck itself submitted a report based on its clinical trials to the FDA explaining the clinical history that had led Merck initially to limit experimental doses for osteoporosis to 20 mg or less. C.A. App. 4060, 635-36, 639-40.

After the "side effect" incidents, Merck launched introspective studies to investigate the gastrointestinal side effects of alendronate and improve the treatment methods. Based on animal studies, Merck's inventors postulated that increasing dose size while decreasing frequency to weekly dosing might be as well or even better tolerated than the existing daily dosing regi-

men. The inventors first formulated this idea in May 1996. C.A. App. 610-611, 621. Because weekly dosing was one of many alternatives being advanced at Merck in 1996, the idea – which the Federal Circuit would later insist had been "obvious" – faced substantial skepticism within the company and was laid aside. *Id.* at 617-22. Only in mid-1997, after additional animal studies confirmed their thesis, did the inventors apply for a patent directed to administering sevenfold the daily dose on a weekly basis. *Id.* at 620-23, 713-14.

Until Merck's once-weekly studies, undertaken after the invention resulting in the '329 patent, no clinical investigator reported exposing osteoporotic women to unit doses over 20 mg of alendronate. Even statements by Teva before this lawsuit confirm the widespread perception and understanding of those skilled in the art about the potential for gastrointestinal injuries from high doses. C. A. App. 4414 (c.3, l.12-25, 34-43). The suggestion that a sevenfold dose would not increase gastrointestinal side effects seemed as surprising – at the time – as a suggestion that eating a whole pizza on Sunday night would cause no more heartburn than eating one slice of pizza a day.

The PTO issued Merck's '329 patent in 1999. Even though Teva could not enter the market until 2008, Teva recognized the superiority of Merck's "once-weekly" product, and filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to copy Merck's once-weekly 70-mg and 35-mg FOSAMAX® tablets before the expiration of the patent. In response, Merck filed this infringement suit under 35 U.S.C. § 271(e)(2).

B. The District Court Proceedings

Following a four-day bench trial, the district court ruled for Merck in an exhaustive opinion citing evidentiary support for the court's factual findings and making credibility determinations. App., *infra*, 43a-99a. Judge Farnan found that Merck provided an express definition in the specification of the disputed phrases in the claims (*id.* at 58a-62a) and rejected Teva's expert's contrary construction as unpersuasive (*id.* at 62a-64a). Teva sought to prove that a July 1996 article in a publication

called the *Lunar News* anticipated Merck's invention. Judge Farnan, however, rejected that contention as a matter of fact. *Id.* at 65a-73a. He also concluded that that *Lunar News* article and another similar article could not render the claims obvious. *Id.* at 73a-91a He further found that Merck's secondary considerations strongly weighed in favor of his ultimate legal conclusion that the invention was not obvious. *Id.* at 91a-94a..

1. The Claim Construction Issue

The district court held that the '329 patent expressly defines the "about 70 mg" and "about 35 mg" phrases by explaining that the terms account for the variability in active ingredient weight that would result from the use of alendronic acid derivatives. App., *infra*, 61a-62a. The specification says:

> Because of the mixed nomenclature currently in use by those of ordinary skill in the art, reference to specific weight * * * of a bisphosphonate compound in the present invention is on an acid active weight basis * * *. For example, *the phrase* "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis" *means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.*

C.A. App. 3594-95 (c10, l.65, to c.11, l.8) (emphasis added). The patent specification was exceptionally clear as to the meaning of the "about" phrase: any mention of a "specific weight" was to be standardized by reference to its acid form.

As defined by the specification, the "about 70 mg" and "about 35 mg" phrases adjust the weight of the active ingredient by taking into account variances in molecular weight for alendronic acid derivatives. As construed by the district court, the claim language requires that the amount of the alendronic acid derivative in the tablet be adjusted so that the tablet contains the same number of alendronate core molecules as 70 or 35 mg of alendronic acid. App., *infra*, 62a.

Attempting to parse the individual words from the defined phrase, Teva argued that "about" simply meant "approximately" – as if the patent had made no attempt to define the phrases that contain the word "about." The district court recognized that Teva's proposition that "about" means "approximately" was utterly implausible given that the patent's examples carefully denote the resulting quantity of alendronate derivative for its formulations to one-hundredth of a milligram. See App., *infra*, 62a-64a.[4]

The word "about" was placed within the quotation marks circumscribing the phrase being defined. See page 7, *supra*. The specification defines the phrase within the quotation marks as being calculated "based on 70 mg" and not "based on about 70 mg." Teva's construction required casting aside the patent's precise definition and moving the term "about" outside the quotation marks of the defined phrase or inserting the term "about" into the "based on 70 mg" definition.

Even Teva's expert, Dr. Russell, reluctantly but unambiguously accepted the '329 patent's explicit definition:

> Q. But they gave you that exact definition; correct?
>
> A. It's a curious use of the English language.
>
> Q. I understand, but it is what it says, and perhaps the person wanted to say if it's a certain salt one, you might use 71, and if it's a certain salt 2, you might use 73. Isn't that what's indicated in this?
>
> A. Possibly.

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[4] By accounting for the differences in the weights of alendronate derivatives, such usage is precise, not approximate. Examples 7 and 8 in the '329 patent provide for "about 35 mg of alendronate, on an alendronic acid active basis" and "about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis." C.A. App. 3599 (c19, l.13-15, 44-45). Those examples show that the adjusted weight for the alendronate derivative used is 45.68 mg and 91.35 mg respectively. *Id.* (c.19, l.20, 51).

Q. But that's what the definition says; right?

A. *That is the definition as it's described in the patent.*

C.A. App. 432-35 (emphasis added). Relying on both intrinsic and extrinsic evidence, the district court rejected Teva's construction based on the term "about." App., *infra*, 61a-64a.

2. Teva's Invalidity Defenses

Teva's invalidity defenses centered around two articles in the *Lunar News*. C.A. App. 3655-90. As the district court found, the *Lunar News* was not a scientific publication, but a quarterly newsletter of short, unattributed articles about multiple topics, published as a marketing tool by Lunar, a bone densitometer manufacturer. App., *infra*, 70a & n.1; C.A. App. 222-23, 321-22, 4957, 4959-60. Dr. Richard Mazess, Lunar's CEO, wrote most of the articles. C.A. App. 4954-56.

Dr. Mazess's one-page article entitled "Update: Bisphosphonate" in the July 1996 *Lunar News* observed that "[s]ome United States physicians are reluctant to treat because of: a) side effects; b) difficulty of dosing; and c) high costs ($700/year)." A3677. Near the end, without any supporting citation, that article suggests that "[e]ven alendronate potentially could be given in a 40 or 80 mg dose once/week to avoid dosing problems and reduce costs." *Id.*

The district court expressly found that "the prior art cited * * * demonstrates that the suggestion to give 40 or 80 mg of alendronate sodium to treat or prevent osteoporosis was not clinically useful or obvious in July 1997 because of the known dose-related gastrointestinal side effects." App., *infra*, 89a-90a. Moreover, even looking only at the two *Lunar News* articles,[5] the district court found that, "in light of the [clinical] case re-

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[5] Teva relied on a *Lunar News* article from April 1996, as well as the July 1986 article, in its obviousness defense. C.A. App. 3641. Suffering from even more defects than the July 1996 issue, the April 1996 *Lunar News* did not disclose any doses at all and failed to address the well-known expectation of gastrointestinal side effects with higher doses. *Id.*

ports, and the Chestnut study, in conjunction with observations written about alendronate by Dr. Fleis[c]h,[*] * * * the *Lunar News* references did not render the seven-fold daily dose of alendronate * * * obvious given the clearly documented and known dose related gastrointestinal side effects associated with high doses (over 20 mg) of oral alendronate." App., *infra*, 91a.

Those factual issues were disputed at trial, and were the subject of much evidence and expert testimony. The district court found that the evidence established that persons skilled in the art at the time of Merck's invention would have been skeptical of the *Lunar News* suggestion to try 40- and 80-mg doses in light of the dose-related gastrointestinal problems. App., *infra*, 90a. The support for that finding came from the trial evidence from the acknowledged experts in the art, including Drs. Papapoulos, Chestnut, Fleisch, and Fennerty, and even Teva's Dr. Russell. The district court expressly noted that Dr. Fennerty was "very credible" when explaining why any physician would have been "extraordinarily concerned" to suggest a 40- or 80-mg dose for osteoporotic patients. *Id.*

In contrast, the district court recognized that Dr. Mazess, the author of the *Lunar News* articles, "[did] not possess an MD, has no formal training in pharmacology, and obtained his bachelors degree and Ph.D in anthropology." App., *infra*, 70a n.1. Given that Judge Farnan also found for purposes of the *Graham* factors that a person of ordinary skill in the art was "an individual who would have an M.D. and/or Ph.D. and was working in the field of and doing research on osteoporosis" (App., *infra*, 84a), Dr. Mazess's expertise fell short of the osteoporosis treatment experts that were the source of the other evidence at trial. To rule in Merck's favor, the district court did not have to go so far as to deem Dr. Mazess not an expert at all; rather, it sufficed to find Dr. Mazess *less credible* than other experts – just what finders of fact do in all types of complex cases.

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[*] As the district court recognized, Dr. Fleisch is known as the "father of bisphosphonates" due to his extensive work and authorship of the leading treatise in the field. App., *infra*, 85a.

Finally, the district court found that "the significant secondary considerations offered by Merck undermine any claim of obviousness." App., *infra*, 94a. The court found Merck's expert testimony "persuasive" in explaining the increased sales after the launch of the once-weekly FOSAMAX® product, without any corresponding increase in expenditures, and noted a sharp increase in physician adoption of FOSAMAX® after introduction of the weekly regimen. App., *infra*, 91a-92a. In contrast, the district court found Teva's expert to be "unpersuasive." App., *infra*, 93a.

C. Proceedings In The Federal Circuit

In a 2-1 decision, the Federal Circuit reversed the district court's judgment, disagreeing with its claim construction and holding the asserted claims invalid for obviousness as a matter of law. See App., *infra*, 2a.

1. The Reversal On Claim Construction

In reversing the district court's claim construction, the court first redefined the parties' dispute as being over the meaning of the word "about" rather than the entirety of the phrases in the claims where that term appears. Declaring the definition of those phrases in the specification "ambiguous," the Federal Circuit believed itself free to give "about" its ordinary meaning of "approximately" because the specification had not redefined that term. App., *infra*, 2a, 10a & n.7, 15a.

But the meaning of the term "about" was never in issue at the trial and was never litigated. The entirety of the phrase was the issue. To sidestep Merck's irrefutable position about what the words of the patent specification actually say, the majority simply declared that the drafters made a mistake: "While Merck's grammatical savvy is noted, we believe that the omission of a second 'about' is likely an inadvertent error rather than the product of meticulous claim drafting." App., *infra*, 13a n.8. Not even Teva had asserted such an inadvertent drafting error, and there was *no* evidence to suggest one.

2. The Reversal Of The Nonobviousness Holding, Including The Nullification Of Merck's Demonstrated Commercial Success Evidence

Separately, the Federal Circuit held that Merck's two claims were invalid as a matter of law in light of the two *Lunar News* articles by reaching its own conclusion of obviousness, and then globally reweighing the evidence, making new findings on appeal, and – with unusual candor – universally rejecting contrary findings as "clearly erroneous." See, *e.g.*, App., *infra*, 22a (emphasis added) ("*to the extent* that the district court interpreted the scope of the prior art *otherwise*, that was clear error"). That inverted approach to reviewing the district court's strict and careful adherence to this Court's *Graham* factors accorded no deference to the district court's detailed findings on several pivotal and clearly disputed factual issues.

In addition, the Federal Circuit took a surprising approach to the law of secondary considerations – law emanating from *this* Court's *Graham* v. *John Deere* decision and numerous even earlier decisions of this Court. The court declared that Merck's dramatic "commercial success" evidence had "no force" on the ground that Merck's prior existing patent had "legally barred" anyone else from pursuing or testing any improvements to Merck's prior "daily" invention. App., *infra*, 23a-24a. Under that approach, an existing patent owner could ever prove commercial success of an improvement patent, in the pharmaceutical field or any other field.

3. The Dissenting Opinions

a. Judge Rader's Dissent

Judge Rader dissented from the panel decision, asserting that "[t]his case shows the consequences of paying only lip service to the often-cited, but rarely-followed lexicographer rule and the basic jurisprudential principle of according trial courts proper deference." App., *infra*, 26a. He observed that the Federal Circuit's claim construction rules are used as either "a subtle way for judges to impose their own semantic subjectivity

on claim terms" or "a way for judges to import limitations not included in the claims." *Id.*

Judge Rader explained why the word "about" was inseparable from the entire phrase defined in the specification, and pointed out that the specification set off the entire phrase in quotation marks, including the term "about," and expressly stated what that phrase "means" for purposes of the patent. App., *infra*, 28a-29a. Judge Rader understood that the specification explained why the phrase was being defined – "[b]ecause of the mixed nomenclature currently in use by those o[f] ordinary skill in the art" – and revealed the scientific reason for including "about" in its definition – "[a] salt or a mixture may require a different weight to achieve the same number of bisphosphonate molecules present in 70 mg of alendronate." *Id.* at 29a-30a.

Judge Rader concluded by decrying his own court's inability or refusal to give deference to the efforts and conclusions of district courts in matters of claim construction. "This was the classic 'close case,' so close in fact that ultimately two federal judges (one of whom conducted an entire bench trial on this issue) and the United States Patent and Trademark Office agreed with [Merck] and two federal judges agreed with [Teva]." App., *infra*, 32a. Despite the district court's "superior tools and time" to evaluate the record, the witnesses, and the evidence, he noted that the Federal Circuit often "becomes enamored with its own analysis of a very close issue and reverses the district court." *Id.* As he put it, the court has a double-edged "'truth in advertising' problem" when it comes to giving deference to district courts. *Id.* at 33a-34a.

b. The Dissent Of Three Additional Judges

Judge Lourie, joined by Chief Judge Michel and Judge Newman, dissented from the denial of rehearing en banc. App., *infra*, 38a-39a. In their view, the panel majority erroneously concluded that commercial success is not probative because "others were legally barred" from commercially testing certain ideas and because the majority erred in linking commercial success to the failure of others. App., *infra*, 38a.

Judge Lourie explained that "[c]ommercial success is a question of fact, and, once it is established, as found here by the trial court, the only other question is whether the success is attributable to the claimed invention ('nexus')." App., *infra*, 38a. In the view of those dissenting judges, "[t]he panel's rule is especially unsound in the context of an improvement patent, as here, because it holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention." *Id.* at 38a-39a. "[T]he full court should have reheard the appeal to eliminate the confusion in the law that the panel opinion creates." *Id.* at 39a.

REASONS FOR GRANTING THE PETITION

When Congress created the United States Court of Appeals for the Federal Circuit in 1982, it centralized the *appellate* function in patent cases. The *trial* function remains with district courts around the country, following normal trial procedures. Nothing gives the Federal Circuit more reason than any other appellate court to substitute its judgment on *factual* issues for that of a district court that has held a trial. Yet the Federal Circuit is doing just that – by allocating to itself the power of *de novo* review, by giving lip service to the "clearly erroneous" rule but then transparently failing to apply it, and most recently by robbing of all substance an important criterion established by this Court for determining obviousness.

All of this has provoked howls of outrage from some of the Federal Circuit's own judges. See App., *infra*, 26a (Rader), 38a-39a (Lourie); *Phillips* v. *AWH Corp.*, 376 F.3d 1382, 1384 (Fed. Cir. 2004) (Mayer, C.J., dissenting from en banc order) ("Until the court is willing to reconsider its holdings * * * that claim construction is a pure question of law subject to *de novo* review in this court, any attempt to refine the process is futile. * * * [S]huffling our current precedent merely continues a charade * * *."); *Phillips* v. *AWH Corp.*, No. 03-1269, 2005 WL 1620331, at *22-*26 (Fed. Cir. July 12, 2005) (en banc) (Mayer, J., dissenting). There is a war on within the Federal Circuit, and only this Court can stop the fighting and bring the Federal

Circuit's approach to factual issues in line with the approach of other appellate courts.

The open disagreement among judges of the Federal Circuit suggests that now is a particularly appropriate occasion for this Court to oversee how that court is handling its exclusive appellate docket. In 1986 this Court felt constrained to remind the Federal Circuit of the proper role of appellate courts in reviewing findings of fact. *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. 809, 811 (1986). The Federal Circuit has not been alone in needing such supervision from this Court for failing to defer on factual issues.[7] Moreover, this is a case in which the standard of review mattered – the district court's exhaustive opinion, heavily dependent on factual findings including credibility determinations after a trial, could not have been reversed on either claim construction or obviousness by a court truly engaged in deferential review of the facts. And one of the most important patents in the pharmaceutical field has been invalidated because the Federal Circuit overstepped its bounds.

Furthermore, this case usefully complements *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996). In that case this Court almost a decade ago held that patent claim construction is an issue exclusively for "the court" but said nothing to indicate whether "the court's" findings following a trial should be reviewed deferentially – as factual findings underlying an issue reserved for judicial determination usually are. See, *e.g.*, *Ornelas* v. *United States*, 517 U.S. 690, 699 (1996); *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 402 (1990); *Pierce* v.

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[7] See, *e.g.*, *Amadeo* v. *Zant*, 486 U.S. 214, 223 (1988); *Icicle Seafoods, Inc.* v. *Worthington*, 475 U.S. 709 (1986); *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985); *Inwood Labs., Inc.* v. *Ives Labs., Inc.*, 456 U.S. 844 (1982); see also *Ornelas* v. *United States*, 517 U.S. 690, 699 (1996) (after holding that the standard of appellate review of ultimate determinations of probable cause or reasonable suspicion is *de novo*, "hasten[ing] to point out that a reviewing court should take care • • • to review [underlying] findings of historical fact only for clear error"). See generally 1 CHILDRESS & DAVIS, FEDERAL STANDARDS OF REVIEW § 2.08 (3d ed. 1999).

Underwood, 487 U.S. 552, 560 (1988); *Miller* v. *Fenton*, 474 U.S. 104, 114-115 (1985).

The court compounded its lack of deference by announcing an erroneous, new, and far-reaching principle of law that the commercial success criterion announced in this Court's cases can be disregarded whenever a patentee obtains an improvement patent. On all three questions presented, the Federal Circuit has decided important issues contrary to this Court's precedents, and this case presents an excellent vehicle for addressing Federal Circuit practices that have become problematic as the court regularly reverses district courts' proper, fact-dependent holdings on both claim construction and obviousness.

I. This Court Should Review The Federal Circuit's Strident But Erroneous View That There Is No Evidentiary Factfinding In Patent Claim Construction

The Federal Circuit's *de novo* standard of review as applied indiscriminately to facts underlying claim construction has afforded that court the extraordinary license to reverse district court findings that could not have been reversed under any other standard. The *de novo* standard, adopted by the Federal Circuit in two en banc decisions and recently reaffirmed en banc, is ripe for this Court's review. The standard is plainly wrong, and this case presents an excellent vehicle for reviewing it.

A decade ago, the Federal Circuit held in *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 897 (Fed. Cir. 1995) (*Markman I*), aff'd in part, 517 U.S. 370 (1996) (*Markman II*), that "the interpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court." 52 F.3d at 970. The en banc also declared that there were no findings of fact to be made by a court (*id.* at 981 (emphasis added)):

> Through this process of construing claims by, among other things, using certain extrinsic evidence that the court finds helpful and rejecting other evidence as unhelpful, and resolving disputes en route to pronouncing the meaning of

> claim language as a matter of law based on the patent documents themselves, *the court is not crediting certain evidence over other evidence or making factual evidentiary findings.* * * * The district court's claim construction, enlightened by such extrinsic evidence as may be helpful, is still based upon the patent and prosecution history. *It is therefore still construction, and is a matter of law subject to de novo review.*

In *Markman II*, this Court held that "the construction of a patent * * * is exclusively within the province of the court," 517 U.S. at 372, but did not call the question one of law or address the standard of appellate review. Instead, this Court focused on allocating claim construction as between court or jury, and concluded that "judges, not juries, are the better suited to find the acquired meaning of patent terms." *Id.* at 388. The Court unmistakably focused, however, on the claim construction task as performed by *trial* judges (*id.* at 389-90 (emphasis added)):

> [I]n these cases a jury's capabilities * * * are much less significant than a trained ability to ***evaluate the testimony*** in relation to the overall structure of the patent. The decisionmaker vested with the task of construing the patent is in the better position to ascertain whether an expert's proposed definition fully comports with the specification and claims and so will preserve the patent's internal coherence. We accordingly think there is sufficient reason to treat construction of terms of art like *many other responsibilities that we cede to a judge in the normal* ***course of trial, notwithstanding its evidentiary underpinnings***.

Nonetheless, again sitting en banc in *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998), the Federal Circuit announced that under *Markman II* it was permitted to "review claim construction *de novo* on appeal including any allegedly fact-based questions."

The Federal Circuit insists that claim construction is a question of law for the court, and that it follows that the appellate court is entitled to give all aspects of claim construction *de novo*

review without deference to factual findings. Those concepts are not the same, however, and not all questions reserved for the court are reviewed *de novo*. Indeed, there is no reason why claim construction should be different in this regard from patent validity, as to which this Court has emphasized that "the ultimate question * * * is one of law," but pointed out in the same sentence that a subsidiary question "lends itself to several basic *factual* inquiries." *Graham*, 383 U.S. at 17 (emphasis added). Just as *Graham* acknowledged factual inquiries underlying obviousness, *Markman II* acknowledged "evidentiary underpinnings" of claim construction, 517 U.S. at 390. The two issues should receive parallel treatment.

Last month, the Federal Circuit issued its eagerly awaited en banc decision in *Phillips* v. *AWH Corp.*, No. 03-1269, 2005 WL 1620331 (Fed. Cir. July 12, 2005). Despite numerous amicus briefs urging it to abandon the holdings of *Markman I* and *Cybor*, the court without substantive comment, and over vehement dissent, "decided not to address that issue at this time * * * [and] therefore le[ft] undisturbed [its] prior en banc decision in *Cybor*." 2005 WL 1620331, at *20. The three en banc holdings that there is no deference-worthy factual component to claim construction are the source of the Federal Circuit's current and internally recognized quagmire.

The fiction that district courts never weigh evidence or find facts when deciding the meaning of patent claims has – in little more than a decade – proved itself to be unworkable and increasingly arbitrary.[8] The most recent and comprehensive study

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[8] See *Phillips* v. *AWH Corp.*, 376 F.3d at 1384 (Mayer, C.J., dissenting from en banc order) ("Nearly a decade of confusion has resulted from the fiction that claim construction is a matter of law, when it is obvious that it depends on underlying factual determinations which, * * * if disputed, are * * * reviewable on appeal for clear error."); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("Now more than ever I am convinced of the futility, indeed the absurdity, of this court's persistence in adhering to the falsehood that claim construction is a matter of law devoid of any factual component. * * * [A]ny attempt to fashion a coherent

of all Federal Circuit decisions since *Markman II* through 2003 calculated that the reversal rate for appealed claim terms is 34.5%. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 233 (2005) (citing other empirical studies). That extremely high reversal rate is well over three times the average for all circuits combined, which has been below 10% each year between 2001 and 2004.[9] Professor Moore concluded that "[t]he problem is getting worse, not better," noting that, since *Markman II*, there should be more predictability in claim construction, not less, and the reversal rate should be going down, not up, but the opposite is true in both respects. *Id.* at 245-47.

Not only has the Federal Circuit's flawed premise that there is no fact finding in claim construction directly caused increased unpredictability, uncertainty, litigation costs, and reversal rates, but also it has damaged the court's credibility and legitimacy in the eyes of both litigants and district courts. *Phillips*, 2005 WL 1620331, at *24 (Mayer, J., dissenting) ("that claim construction is dependent on underlying factual determinations has been verified by our experience, which shows that reviewing these questions de novo has not clarified the law, but has instead distort[ed] the appellate process, causing confusion among the district courts and bar") (internal quotation marks omitted). Any hope that the Federal Circuit's *en banc* decision in *Phillips* might confront the real problem ended when the court declined to disturb its prior decision in *Cybor*. See 2005 WL 1620331, at *20. Hence, the Federal Circuit's unjustifiable fiction authorizing its form of "*de novo* review" should not escape this Court's oversight any longer.

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standard under this regime is pointless, as illustrated by our many failed attempts to do so * * *.").

[9] See http://www.uscourts.gov/caseload2004/tables/B05Mar04.pdf; http://www.uscourts.gov/caseload2003/tables/B05Mar03.pdf; http://www.uscourts.gov/caseload2002/tables/B05Mar02.pdf; http://www.uscourts.gov/caseload2001/tables/B05Mar01.pdf.

To be sure, construing patent claims involves construing a written instrument, a task better allocated to judges than to juries. But that does not mean claim construction has no factual component. As a matter of substantive patent law, the issue is not what the claims *mean to judges*, but what they mean to "those skilled in the art to which the invention pertains or with which it is most nearly connected." *Phillips*, 2005 WL 1620331, at *5 (opinion of the court) (quoting *In re Nelson*, 280 F.2d 172, 181 (CCPA 1960)). That is a matter most frequently resolved by weighing evidence, not by parsing legal principles. Factual, not legal, inquiry is necessary to educate a court about the views of those skilled in the art, especially because "patentees frequently use terms idiosyncratically" (*Phillips*, 2005 WL 1620331, at *6), as was done in this case. It follows that the standard of appellate review is that usually applied to factual findings underlying a question for the court. See note 7, *supra*; pages 15-16, *supra*; *Phillips*, 2005 WL 1620331, at *23 (Mayer, J., dissenting). For the Federal Circuit to hold otherwise, simply because it believes the *ultimate* issue is one of law, is nothing but a power grab away from district judges.[10]

Even with proper deference accorded to district courts under Rule 52(a), some claim construction issues may be decided as a matter of law, when, for example, the patent itself and other evidence show that there is only one *reasonable* way to construe the affected term.[11] In other instances, however, a pat-

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[10] See App., *infra*, 32a-34a (Rader, J.., dissenting); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("This court was created for the purpose of bringing consistency to the patent field. * * * Instead, we have taken this noble mandate, to reinvigorate the patent and introduce predictability to the field, and focused inappropriate power in this court. * * * [T]he resulting mayhem has seriously undermined the legitimacy of the process, if not the integrity of the institution.").

[11] Ironically, this was such a case. Yet the majority dismissed the only reasonable reading of the patent's explicit definition as mere "grammatical savvy," and insisted on substituting its judgment that there was an "inadvertent error" for the judgment of the district court, the words of the patent, and the expert testimony. App., *infra*, 13a n.8. By disregard-

ent's intrinsic evidence will be obscure or inconclusive. Shortly after *Markman I*, the Federal Circuit in *Hoechst Celanese Corp.* v. *BP Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996), reviewed the intrinsic evidence, experimental data, expert testimony, and dictionaries to determine the meaning of the disputed term in the specification's definition, while being careful to say that it did not accord any deference to the district court's findings or credibility determinations. Nevertheless, the Federal Circuit conceded it was "necessary to rely on the evidence presented at the trial and credit certain evidence over other evidence" when construing claims. *Id.* at 1579. That is what all courts do in such situations, even if the Federal Circuit's en banc decisions in *Cybor* and *Markman I* insisted they do not.[12]

A court's determination of the meaning of a disputed claim phrase, in an environment that requires consideration of what the claim terms meant to a person of skill in the art at the time, inevitably involves weighing conflicting evidence. Here, for example, Judge Farnan explicitly found Teva's expert "unpersuasive." App., *infra*, 64a. Resolving such conflicts requires factfinding, the prototypical task for which district courts are best suited and entitled to deference. See *Zenith Radio Corp.* v.

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ing the patent's definition in its entirety, the Federal Circuit gutted a patentee's ability to act as its own lexicographer to avoid the uncertainties of a future contested claim construction. See App., *infra*, 26a-32a (Rader, J., dissenting).

[12] See App., *infra*, 32a (Rader, J., dissenting) ("Despite the district court's superior tools and time to evaluate the complete record, to hear and inquire from expert and fact witnesses, to delve into countless related details, to probe the scientific and semantic context, and to entertain argument as long as necessary for clarity, this court with its reading three briefs before its half-hour hearing becomes enamored with its own analysis of a very close issue and reverses the district court."); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("[A]fter * * * whipping the bar into a frenzy of expectation, we say nothing new, but merely restate * * * that we will decide cases according to whatever mode or method results in the outcome we desire * * *. [T]here can be no workable standards by which this court will interpret claims so long as we are blind to the factual component of the task.").

Hazeltine Research, Inc., 395 U.S. 100, 123 (1969). What this Court said last Term about tax cases is no less true of patent cases: "The officer who hears witnesses and sifts through evidence in the first instance will have a comprehensive view of the case that cannot be conveyed full strength by a paper record." *Ballard* v. *Comm'r*, 125 S. Ct. 1270, 1283 (2005). "It is, of course, true that credibility judgments have to be made about the experts who testify in patent cases" (*Markman II*, 517 U.S. at 389), and that fact – although no reason to assign factfinding to juries – is very much a reason to review deferentially on appeal the factual component of claim construction. One month after *Markman II*, this Court announced a *de novo* standard of review for probable-cause determinations in search-and-seizure cases but insisted on "clear error" review for "findings of historical fact." *Ornelas*, 517 U.S. at 699. This Court's opinions thus disprove the Federal Circuit's inference that, because claim construction is for the court, *de novo* review applies to all aspects of the issue.

This "standard of review" controversy generated by the Federal Circuit's en banc precedent extends well beyond the enormous dollars at issue in this case. This case provides an excellent vehicle to resolve the dispute within the Federal Circuit and rampant within the affected legal community over whether district courts engage in factfinding subject to Rule 52(a) when construing the meaning of patent claims.[13] When the judicial

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[13] In addition to the strong disagreement within the Federal Circuit reflected by the dissenting opinions in the en banc cases, see, *e.g.*, *Lucas Aerospace, Ltd.* v. *Unison Indus., L.P.*, 890 F. Supp. 329, 333-34 (D. Del. 1995) ("when the Federal Circuit Court of Appeals states that the trial court does not do something that the trial court does and must do to perform the judicial function, that court knowingly enters a land of sophistry and fiction"); Burgess, Comment, *Simplicity At The Cost Of Clarity: Appellate Review Of Claim Construction And The Failed Promise of Cybor*, 153 U. PA. L. REV. 763 (2004); Zura, *Looking For Fire Amidst The Smoke – Is The Federal Circuit Really Exceeding Its Appellate Authority In Patent Infringement Cases?*, 12 U. BALT. INTELL. PROP. L.J. 1 (2003); Staheli, Comment, *Deserved Deference: Reconsidering*

process for claim construction allows the Federal Circuit to invent a factual premise advanced by no party and supported by no evidence – that an inadvertent drafting error took place (App., *infra*, 13a n.8) – it becomes clear that factfinding is occurring in the wrong court. And when the Federal Circuit supplants the trial court's plausible choice between two reasonable interpretations of Merck's "ambiguous" definition for the disputed phrase in claims 23 and 37 (App., *infra*, 13a), it is apparent that the deferential review provisions of Rule 52(a) are being ignored.[14] As Judge Rader noted, "In this case, this court eschews all deference, a particularly striking choice in the face of a very close case and a district court whose diligent and intelligent process and resolution earned more respect than it received." App., *infra*, 33a (dissenting opinion).

The Federal Circuit will never voluntarily relinquish its self-granted power of unrestricted review. See App., *infra*, 10a n.7; *Phillips*, 2005 WL 1620331, at *20. The Federal Circuit has begun expanding its flawed "*de novo*" rationale into other areas of patent law "related to" claim construction. See, *e.g.*, *Exxon Research & Eng'g Co.* v. *United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001) (holding the invalidity defense of indefiniteness was sufficiently tied to claim construction that it did

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The De Novo Standard Of Review For Claim Construction, 3 MARQ. INTELL. PROP. L. REV. 181 (1999).

[14] In a footnote, the majority defensively asserted that "[i]t makes no difference to this conclusion [of invalidity] whether the court begins with the claim construction set forth by the panel or the dissent." App., *infra*, 16a n.10. Clearly, however, the parties' claim constructions were different, both could not have been right, and there is no question that obviousness can be properly determined only in view of the correct claim construction. The Federal Circuit, indeed, contradicted its own footnote by beginning its obviousness discussion by saying, "*In light of* the corrected claim construction we find reversible error in the district court's obviousness analysis." App., *infra*, 15a (emphasis added). If claim construction truly did not matter, the issue would not have been hotly litigated throughout this case and the Federal Circuit would not have addressed that issue at length on appeal.

not involve underlying issues of fact) (citing *Cybor*). Thus, as further evidenced by its obviousness ruling in this case, the Federal Circuit's basic misunderstanding of "*de novo* review" is not confined to claim construction issues, but infects that court's approach to anything that it perceives as a "legal issue." This Court should not wait to correct that entrenched and erroneous practice.

II. The Court Should Review The Federal Circuit's Practice Of Using Its *De Novo* Review Of Legal Issues To Reweigh Evidence And Substitute Its Views For A District Court's Factual Findings

In *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. at 811, this Court summarily vacated a Federal Circuit decision that had reversed a district court's holding of obviousness, noting that the determinations on the *Graham* factors and secondary considerations (including commercial success), "at the least, ought to be subject to [Rule 52(a)]." Now, almost 20 years later, the Federal Circuit needs a refresher course.

Of course, since 1986, the Federal Circuit's decisions on obviousness have routinely cited Rule 52(a) and the *Graham* factors. See App., *infra*, 8a, 16a. Just as routinely, however, the Federal Circuit pays lip service to Rule 52(a) but then reweighs the conflicting evidence to conform to its own conclusion on the ultimate legal issue. See App., *infra*, 26a (Rader, J., dissenting).

This case is the latest and most striking example of a bench trial nullified by the Federal Circuit's self-granted license to review findings of fact without any real deference.[15] As its own opinion in this case illustrates, the Federal Circuit arrives at its outcome, and then globally mows down any contrary finding with a declaration of clear error. That result-oriented approach

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[15] See Rooklidge & Weil, *Judicial Hyperactivity: The Federal Circuit's Discomfort With Its Appellate Role*, 15 BERKELEY TECH. L.J. 725 (2000) (explaining the Federal Circuit's increasing tendencies toward appellate factfinding, creating new records on appeal, and raising new arguments on its own, citing illustrative cases).

of first deciding the legal issue *de novo* and then going back to review the underlying factual determinations cannot possibly accord the proper Rule 52(a) deference to a district court's findings on disputed factual issues. See App., *infra*, 32a-34a (Rader, J., dissenting).

"If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently." *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 573-74 (1985). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Id.* at 574. Here, the district court's exhaustive findings on disputed factual issues reached after a fully litigated bench trial could not have been legitimately cast aside.

For present purposes, this Court need only recognize that the district court's factual findings are both plausible and fully supported by the cited evidence and expert testimony. See App., *infra*, 90a (finding Merck's expert "very credible"); *id.* at 93a (finding Teva's expert "unpersuasive"). "When findings are based on determinations regarding the credibility of witnesses, Rule 52(a) demands even greater deference to the trial court's findings." *Bessemer City*, 470 U.S. at 565.

But the Federal Circuit did more than substitute one plausible set of findings for the district court's different findings. The district court found that persons skilled in the art at the time of Merck's invention would have been skeptical of the *Lunar News* suggestion to try 40- and 80-mg doses in light of the dose-related health problems. App., *infra*, 90a. The Federal Circuit accepted that finding (App., *infra*, 19a), but then proceeded to elevate Dr. Mazess's alleged expertise over all others, holding that "the district court failed to give proper credit to the fact that Dr. Mazess was an expert in osteoporosis." App., *infra*, 22a. Any such issue of "proper credit" is a disagreement on weight, which should not have been revisited on appeal or circumvented simply by declaring Mazess an "expert."

The Federal Circuit's post-trial revision of Dr. Mazess's skill level is disingenuous. Even if Dr. Mazess qualified as an expert, the trier of fact was entitled to find him *less credible* than other experts, and did so. App., *infra*, 90a-91a. The testimony the district court accepted was that the *Lunar News* suggestion would have been incredible to anyone skilled in the relevant art. Hence, only someone unskilled in the relevant art would even have suggested investigating 80-mg doses when everyone with actual skill in the art was unwilling to give osteoporosis patients more than 20 mg.

In making its *Graham* findings on the scope and content of the prior art and the differences between that art and the claimed inventions, the district court properly looked at what a number of individuals skilled in the art knew and examined all of the art before finding that the serious side effect concerns would have rendered the naked suggestion in the *Lunar News* articles to try higher doses "not clinically useful." App., *infra*, 90a. That treatment of those two articles was entirely proper. Even if they had been "published in peer-reviewed journals or authored by one skilled in the art," there could be no clear error in finding that they would not have overcome what one skilled in the art would have understood from the body of prior art as a whole.

Confining its analysis to the two *Lunar News* articles, the Federal Circuit improperly circumscribed the prior art and disregarded everything that taught away from the article's invitation to try. See *United States* v. *Adams*, 383 U.S. 39, 51-52 (1966) (known disadvantages in the prior art which would naturally discourage the search for new inventions may be considered in determining obviousness). Here, because those skilled in the art in 1997 would not have followed the unsupported July 1996 *Lunar News* suggestion, the finding that the *Lunar News* articles could not have overcome the teachings of the prior art as a whole again could not have been clearly erroneous.[16]

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[16] The prior art and the acknowledged skepticism in the art instead created a clear expectation that the *Lunar News* suggestion would fail. Such a demonstrated expectation of failure is the antithesis of a reason-

On appeal the Federal Circuit found that a motivation would have existed to reduce the 80/40-mg dose suggestions in *Lunar News* to the claimed 70/35-mg doses. App., *infra*, 16a-17a. As the district court realized, however, that was not even the correct inquiry. Instead, the relevant analysis was whether there would have been any motivation in the art to increase the dosage beyond the 20-mg level believed to cause unacceptable side effects. App., *infra*, 91a. Not even the Federal Circuit could find that anyone in 1997 would have been motivated to do that, which reveals that any necessary teaching or motivation could have been found only in hindsight.

If there was ever a case in which Rule 52(a) should have compelled accepting a district court's findings, it is this one. This case is therefore an excellent vehicle by which to correct the Federal Circuit's clear misapprehension of the concept and scope of its appellate "*de novo*" review while sparing this Court from becoming bogged down in the underlying factual disputes already plausibly resolved by the district court.

III. This Court Should Review The Federal Circuit's Ruling Nullifying The Probative Value Of A Patentee's "Commercial Success" Evidence Related To Its Improvement Patent

The Federal Circuit also held that the district court "erred in its weighing of secondary considerations of non-obviousness." App., *infra*, 22a. That, too, was not the Federal Circuit's prerogative to reassess. See *Inwood Labs., Inc.* v. *Ives Labs., Inc.*, 456 U.S. 844, 856 (1982) ("Determining the weight and credibility of the evidence is the special province of the trier of fact."). This issue shares with the first two issues the characteristic that the Federal Circuit has unjustifiably substituted its judgment for that of the trier of fact, but it also involves separate *legal* considerations as to which the Federal Circuit departed from this Court's cases.

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able expectation of success. See, *e.g.*, *Boehringer Ingelheim Vetmedica, Inc.* v. *Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003).

The commercial success criterion strongly supported the non-obviousness of Merck's "once-weekly" patent. As noted above, sales of FOSAMAX® skyrocketed following the insight that once-weekly doses could be effective without increased potential for gastrointestinal distress. Judge Farnan appropriately placed "importance" on this factor. App., *infra*, 93a.

In so doing, he followed this Court's cases faithfully. In *Smith* v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876), the Court recognized commercial success as something that could "justify the inference" that an innovation "was, in truth, invention." The Court phrased it more strongly in *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 271 (1916): commercial success, "of itself, is persuasive evidence of * * * invention." In *Graham* v. *John Deere Co.*, 383 U.S. at 17-18, the Court reiterated (following a change in statutory law) that "[s]uch secondary considerations as commercial success" are important, and noted that "failure of others" is a *separate* "secondary consideration[]." See also *Goodyear Tire & Rubber Co.* v. *Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944); *Krementz* v. *The S. Cottle Co.*, 148 U.S. 556, 560 (1893).

This Court, not the Federal Circuit, originated the commercial success criterion, and the Federal Circuit was not at liberty to reduce it essentially to a nullity whenever a patentee obtains an improvement patent. Yet the Federal Circuit declared that Merck's "commercial success" evidence "has *no force* in this case" because "others were legally barred from commercially testing the Lunar News ideas" due to Merck's other patent rights. App., *infra*, 23a (emphasis added). That ignores not only the decisions of this Court's cited above, but also the Constitution. See U.S. CONST. Art. I, § 8, cl. 8. Given that Congress is to "secure[e] for limited times to * * * Inventors the exclusive right to their * * * Discoveries" in exchange for full disclosure so that the public may benefit from and build on the patent's teachings, the Federal Circuit's misplaced reliance on others' having no incentive to improve patented inventions before patent expiration directly undermines

the fundamental purposes of the patent system. See 35 U.S.C. § 101 (patentable inventions include "any new and useful improvement"); *Gen. Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 368 (1938) ("most inventions represent improvements on some existing article, process or machine"); see also *Graham*, 383 U.S. at 7 (Thomas Jefferson's "improvements on plows, to mention but one line of his inventions, won acclaim and recognition on both sides of the Atlantic").

The Federal Circuit's rule nullifying a prior patentee's commercial success evidence will also unjustly discriminate against patentees who continue to enrich the public by improving their inventions. If the rule is allowed to stand, a third party that develops and patents an improvement to an earlier patented invention can support its non-obviousness case by proving commercial success and nexus but the earlier patentee would be foreclosed from doing so. That distinction makes no sense, and threatens to undermine the patent system's basic goals of encouraging innovation and full disclosure to the public.

On that basis alone, the Federal Circuit's far-reaching new rule should be reviewed and reversed. See App., *infra*, 38a-39a (Lourie, J., dissenting). But the Federal Circuit's other justifications for nullifying Merck's strong commercial success evidence for its improved dosing regimen in the '329 patent are equally meritless. For example, the Federal Circuit ignored 35 U.S.C. § 271(e)(1), which provides certain "safe harbors" from infringement for testing of a new drug product. See *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2381 (2005); *Eli Lilly & Co.* v. *Medtronic Inc.*, 496 U.S. 661 (1990). Indeed, Teva was in fact doing research and seeking patents on other alendronate inventions, and had a strong incentive to develop Merck's present invention, both for purposes of licensing Merck and for obtaining its own exclusivities extending beyond the expiration of Merck's '077 patent. The fact that Teva filed an ANDA and challenged the '329 patent rather than waiting to market generic versions of Merck's "once-daily" products is a compelling admission of both the value of Merck's

improved "once-weekly" invention and the evidentiary significance of Merck's commercial success as support for the validity of the '329 patent.

Because the Federal Circuit's rule is based on such clearly flawed premises, it should be reviewed immediately. Because of that court's exclusive jurisdiction, no percolation is needed or likely. The Federal Circuit has already invoked that rule when vacating another commercial success finding supporting a non-obviousness ruling reached after a bench trial. See *Syntex (U.S.A.) LLC* v. *Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005). Citing this case, the Federal Circuit expanded its new rule by stripping commercial success of its longstanding status – based on decisions of this Court – as a unique secondary consideration, declaring that a high degree of commercial success permits merely an inference that others have tried and failed to reach a solution. *Id.* at 1383. No more patentees, cases, or improvements in any field should be subjected to the Federal Circuit's flawed new "commercial success" rule.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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AUGUST 2005

APPENDIX A

United States Court of Appeals for the Federal Circuit

04-1005

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

DECIDED: January 28, 2005

Before RADER, GAJARSA, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA.
Dissenting opinion filed by Circuit Judge RADER.

GAJARSA, Circuit Judge.

Teva Pharmaceuticals USA, Inc. ("Teva") appeals the final judgment of the United States District Court of Delaware, which, after a bench trial, found Merck & Co.'s ("Merck") U.S. Patent No. 5,994,329 (issued Nov. 30, 1999) ("the '329 patent") not invalid as anticipated or obvious. The district court further found the '329 patent to be enforceable, and the '329 patent claims 23 and 37 constructively infringed by Teva's Abbreviated New Drug Application ("ANDA") under 35 U.S.C. § 271 (e)(2)(A) of the Hatch-Waxman Act. Merck & Co., Inc. v. Teva Pharms. USA, Inc., 288 F. Supp.

2d 601 (D. Del. 2003) ("Merck"); Merck & Co., Inc. v. Teva Pharms. USA, Inc., No. 01-CV-0048, *Order* (D. Del. Sept. 24, 2003) (Final Judgment Order Pursuant to Fed. R. Civ. P. 54(b)) ("Final Judgment Order").[1]

We disagree with the district court's construction of the claim term "about" in claims 23 and 37 of the '329 patent. Because we further hold claims 23 and 37 obvious in light of the prior art, we vacate the judgment of the district court and hold the claims invalid and not infringed.

I. BACKGROUND

A. '329 Patent

Merck owns the '329 patent. The '329 patent, entitled "Method for Inhibiting Bone Resorption," teaches a method of treating and preventing osteoporosis through less-than-daily administration of bisphosphonate compounds. '329 patent, col. 1, ll. 15-25. The patent was filed on August 14, 1998, and Merck stipulated at trial that it would not allege an invention date prior to July 22, 1997 for the claims at issue. Merck, 288 F. Supp. 2d at 606.

Bisphosphonates are a family of chemical compounds that are known to selectively inhibit the bone destruction process that contributes to osteoporosis and other bone diseases. '329 patent, col. 1, ll. 45-50. Bisphosphonates include, among other compounds, alendronate, risedronate, tiludronate, pamidronate, ibandronate, zolendronate, and etidronate. Id. at col. 1, ll. 54-65; col. 2, ll. 28-31. At issue in

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[1] On appeal, Teva does not challenge the district court's determination that the '329 patent is enforceable or that it would be infringed by Teva's proposed drug product.

this case are once-weekly dosages of alendronate *monosodium trihydrate*.

Bisphosphonates are not readily absorbed by the gastrointestinal ("GI") tract. The medications thus require rigorous dosing instructions: a patient must take the medicine on an empty stomach and remain upright and fasting for thirty minutes after ingestion. '329 patent, col. 2, ll. 3-24. In addition, the compounds are known to have adverse GI side effects that physicians believed to be related, in part, to (a) irritation to the patient's esophagus, or (b) the size of the dose. Id. at col. 2, ll. 23-46.

Before the '329 patent issued, standard osteoporosis treatments consisted of small daily doses of bisphosphonates to avoid GI complications. Id. at col. 1, ll. 54-61; col. 2, ll. 34-35, 44-46. According to the patent, however, the adverse GI side-effects resulting from repetitive irritation to the GI tract were the primary concern in the field. Id. at col. 2, ll. 65-67; col. 3, l. 57 - col. 4, l. 13. The inventors trumpeted the reduced-frequency dosing schedule disclosed in the '329 patent as decreasing the irritating effect of the compounds, as well as increasing patient compliance with the rigorous dosing instructions. Id. at col. 3, ll. 57-64; col. 4, ll. 14-23.

This case involves dependent claims 23 and 37 of the '329 patent. At trial, the parties agreed to cast the text of these claims in independent form, incorporating all the dependent limitations:

> 23. A method for treating osteoporosis in human comprising orally administering about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

> 37. A method for preventing osteoporosis in human comprising orally administering about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

'329 patent, col. 21, ll. 24-27 (claim 23) (emphasis added); col. 22, ll. 24-26 (claim 37) (emphasis added). We note that the only differences between claim 23 and claim 37 are (1) the dosage amount of alendronate monosodium trihydrate (70 mg or 35 mg) and (2) whether the method is directed to treating or preventing osteoporosis.

Merck has Food and Drug Administration ("FDA") approval to market both a once-weekly and a relatively diminished daily dose of alendronate monosodium trihydrate, which it does under the trade name Fosamax. Merck, 288 F. Supp. 2d at 605.

B. Litigation

In late 2000, Teva amended an existing ANDA and sought FDA approval to market generic versions of Merck's once-weekly Fosamax supplement in 35 mg and 70 mg quantities.[2] Merck, 288 F. Supp. 2d at 605-06; Teva Br. at 4. Merck subsequently filed suit against Teva under 35 U.S.C. §

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[2] Teva filed one amendment for the once-weekly 70 mg dosage, and later filed another for the once-weekly 35 mg dosage. Merck, 288 F. Supp. 2d at 605-06. Merck separately sued Teva for infringement, under 35 U.S.C. § 271 (e)(2)(A), based on each ANDA amendment. Id. The district court consolidated those suits in the present action.

271 (e)(2)(A), alleging Teva's ANDA filing was an act of infringement.[3]

According to the trial court, Merck acted as its own lexicographer and through the specification redefined the ordinary meaning of "about" in claims 23 and 37 - which both parties agree has the ordinary meaning "approximately" - to something quite different. Merck, 288 F. Supp. 2d at 612-16. Thus, the district court concluded the terms "about 35 mg" in claim 37 and "about 70 mg" in claim 23 mean exactly 35 (or 70) mg of alendronic acid.[4]

Relying on this construction of "about," the district court dismissed Teva's allegations that the claims at issue were (1) anticipated by a July 1996 Lunar News article or (2) rendered obvious by an April 1996 Lunar News article combined with the July 1996 article.[5] The trial court found

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[3] The present case relates to another action between the two parties involving Merck's daily formulation of Fosamax. The district court found Teva's proposed generic daily alendronate compound would infringe Merck's patent on that drug, and this court affirmed that decision. Merck & Co. v. Teva Pharms. USA Inc., 347 F.3d 1367 (Fed. Cir. 2003). In this action the parties agreed to be bound by the judgment from this court on issues relating to the daily formulation. As a result, the only issues before the district court in this case related to the '329 patent. Merck, 288 F. Supp. 2d at 606.

[4] That is, the trial court construed "the disputed claim terms 'about 70/35 mg' to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories," Merck, 288 F. Supp. 2d at 616.

[5] Lunar News is a quarterly newsletter distributed to approximately 15,000 to 20,000 physicians and others in the medical art by Lunar Corporation, a manufacturer of bone densitometry equipment used to diagnose osteoporosis. Merck, 288 F. Supp. 2d at 618-19; Teva Br. at 11-12. The author of each article is Dr. Mazess, who has a doctorate degree in anthropology, but does not have formal training in pharmacology. Id.

both articles qualified as prior art publications under 35 U.S.C. § 102(a). Merck, 288 F. Supp. 2d at 618-19. The April 1996 article in Lunar News recommends weekly dosages of alendronate to improve patient compliance:

> [O]ne of the difficulties with alendronate is its low oral bioavailability. When taken with water in a fasting state, only about 0.8% of the oral dose is bioavailable. Even coffee or juice reduces this by 60%, and a meal reduces it by >85%. Alendronate must be taken, after an overnight fast, 30-60 minutes before breakfast. Subjects should remain seated or standing; a very small group of patients have reported some upper gastrointestinal distress if this is not done. This regime may be difficult for the elderly [to] maintain chronically. An intermittent treatment program (for example, once per week, or one week every three months), with higher oral dosing, needs to be tested.

Update: Bisphosphonate, Lunar News, Apr. 1996, at 31 (emphasis added).

The July 1996 Lunar News article further emphasizes the need for a once-weekly dose of Fosamax because "[s]ome United States physicians are reluctant to treat [patients with Fosamax] because of: a) side effects; b) difficulty of dosing; and c) high costs ($700/year)." The author suggests:

Teva points out, however, that Dr. Mazess directed the Bone Mineral Laboratory at the University of Wisconsin, established bone densitometry as a diagnostic tool, founded the first manufacturer of bone densitometry measuring equipment (Lunar), was Lunar's first president, has participated in and designed clinical trials for osteoporosis treatment, and is widely published in the bone disease field.

> The difficulties with oral bisphosphonates may favor their episodic (once/week) or cyclical (one week each month) administration. Even oral alendronate potentially could be given in a 40 or 80 mg dose once/week to avoid dosing problems and reduce costs.[6]

Update: Bisphosphonate, Lunar News, July 1996, at 23 (emphasis added).

Regarding anticipation, the trial court held the July 1996 article does not "expressly or inherently disclose the dosage amounts for alendronate in claims 23 and 37" because there was no evidence that 40 mg and 80 mg of alendronate contains "the same number of alendronate core molecules" as found in 35 mg and 70 mg, respectively, of alendronic acid. Merck, 288 F. Supp. 2d at 618-20.

As for obviousness, the district court concluded the suggestion of weekly treatment was not "clinically useful or obvious in July 1997 because of the known dose-related gastrointestinal side effects" associated with the daily formulation of Fosamax. Merck, 288 F. Supp. 2d at 628. Although it is undisputed that a once-weekly dosage was known to be efficacious, the court determined that the Lunar

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[6] Teva argues that the 40 mg and 80 mg amounts were recommended because 40 mg tablets of alendronate monosodium trihydrate were commercially available for those who suffer from Paget's disease, a bone disorder that also responds to bisphosphonate treatment. The standard daily dose of Fosamax is 5 mg or 10 mg. Exact multiples of the standard daily dose corresponding to the amount of Fosamax administered in a week, i.e., 35 mg or 70 mg, were not commercially available at the time of the 1996 Lunar News articles. Thus, Teva argues, the 40 mg and 80 mg dosages should be viewed as teaching the '329 patent's seven-fold increase in daily dosages (5 and 10 mg), in terms of the 40 mg doses then-available on the market.

News articles could not overcome doctors' concerns associated with higher dosages because the Lunar News articles were not published in peer-reviewed journals or authored by one skilled in the art. Merck, 288 F. Supp. 2d at 628-29.

Finding the '329 patent not invalid as anticipated or obvious, the district court delayed the effective date of the FDA approval of Teva's ANDA until the '329 patent expires and enjoined commercial sale of Teva's generic treatment. Final Judgment Order at 1. This appeal followed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

On appeal from a bench trial, this court reviews the district court's conclusions of law de novo and findings of fact for clear error. Golden Blount, Inc. v. Robert H. Peterson Co., 365 F.3d 1054, 1058 (Fed. Cir. 2004); Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1123 (Fed. Cir. 2000). A finding is clearly erroneous when, despite some supporting evidence, "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." United States v. United States Gypsum Co., 333 U.S. 364, 395 (1948).

The court reviews claim construction, a question of law, de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Obviousness is a question of law based on underlying factual determinations. Richardson-Vicks, Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997). The court reviews an obviousness ruling de novo, but reviews the underlying factual findings for clear error. Graham v. John Deere Co., 383 U.S. 1, 17 (1966); Golden Blount, 365 F.3d at 1058. The underlying factual

determinations include (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of nonobviousness. Graham, 383 U.S. at 17-18.

B. Claim Construction

In finding that Merck acted as its own lexicographer, the district court relied on the following passage from the specification:

> Because of the mixed nomenclature currently in use by those or [sic] ordinary skill in the art, reference to a specific weight or percentage of bisphosphonate compound in the present invention is on an active weight basis unless otherwise indicated herein. For example the phrase "about 70 mg of bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof and mixtures thereof, on an alendronic acid weight basis" means that the amount of bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

'329 patent, col. 10, l. 65 - col. 11, l. 8 (emphasis added). According to the district court's opinion, the patentee uses the phrase "about 35 [or 70] mg" to account for variations in the molecular weight of the different derivatives of alendronic acid and to deliver exactly 35 (or 70) mg of alendronic acid. Merck, 288 F. Supp. 2d at 613. For example, the court noted that alendronate monosodium trihydrate, which is used in Fosamax, requires an atom of sodium for each molecule. Id. at 613-14. If a heavier metal were chosen, such as potassium, the weight of the derivative compound would have to increase to deliver exactly the same number of molecules of

the active alendronate compound found in 35 [or 70] mg of alendronic acid. Id. at 614. The district court thus construed the term "about 35 [or 70] mg" to mean the amount of the derivative compound that gives exactly 35 [or 70] mg of the active compound.

We reverse the district court's construction of "about" and hold that such term should be given its ordinary meaning of "approximately."[7] To properly construe a claim term, a court first considers the intrinsic evidence, starting with the

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[7] The dissent frames the dispute in terms of the entire phrase "about 70 [35] mg of alendronate monosodium trihydrate, on an alendronic acid basis." Post at 2:22-3:2. Notwithstanding this contention, the district court identified the "disputed claim terms" as "about 70 / 35 mg." Merck, 288 F. Supp. 2d at 616. In its brief to this court, Merck likewise stated the issue as whether the district court properly construed the aforementioned limitation (not disputed term) on grounds that the '329 patent expressly defined "about 70 mg" as calculated "based on 70 mg of alendronic acid." See Appellee Br. at 3 (statement of issues). We agree with Merck, and the district court, that the dispute concerns the proper meaning of "about." We thus understand the dissent to argue that meaning is fixed by the context of the claim and the language of the written description.

It is correct to look first to those sources for the meaning at issue. See Vitronics, 90 F.3d at 1582. However, as is noted above when the intrinsic evidence does not clearly establish its own lexicography, it is proper to determine the ordinary meaning of the term. For that reason we ascribe "about" its ordinary meaning here.

Moreover, the dissent pursues a philosophical argument as to the deference which should be given to the trial court. Claim construction being a legal matter it is reviewed de novo and this is still the law notwithstanding the desire of some members of this court to consider creating an exception to that rule. See Cybor, 138 F.3d at 1462-63 (Plager, J., concurring); id. at 1463-66 (Mayer, C.J., concurring in judgment); id. at 1473-75 (Rader, J., dissenting). Therefore, if we apply proper legal precedent as the majority has done in this case, the result is clear and obvious.

language of the claims. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Generally claim terms should be construed consistently with their ordinary and customary meanings, as determined by those of ordinary skill in the art. Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003). While in some cases there is a presumption that favors the ordinary meaning of a term, Tex. Digital Sys. v. Telegenix Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002), the court must first examine the specification to determine whether the patentee acted as his own lexicographer of a term that already has an ordinary meaning to a person of skill in the art. See, e.g., Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1988); Brookhill v. Wilk, 334 F.3d at 1299.

When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description. See, e.g., Bell Atl. Network Servs. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). We have repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term. Id.; see also Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000) ("Absent an express intent to impart a novel meaning, claim terms take on their ordinary meaning."); Renishaw, 158 F.3d at 1249 ("The patentee's lexicography must, of course, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim.") (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)); Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1177-78 (Fed. Cir. 2002) (stating that the "presumption in favor of the claim term's ordinary meaning is overcome, however, if a different meaning is clearly and deliberately set forth in the intrinsic evidence"). In the

present case, the passage cited by the district court from the specification for Merck's definition of "about" is ambiguous. It fails to redefine "about" to mean "exactly" in clear enough terms to justify such a counterintuitive definition of "about."

The phrase's ambiguity arises from the fact that it can easily be read as Teva does - as a way of explaining what is meant by the use of the phrase "alendronate acid active basis" rather than as a way of radically redefining what is meant by "about." The district court construed the phrase "about 70 [or 35] mg" to mean that one should administer approximately 70 (or 35) mg of the derivative compound, such that the end result is that the patient is administered exactly 70 (or 35) mg of alendronic acid. In other words, the district court determined that the quantity specified in the claims (35 or 70 mg) modifies the amount of the derivative compound rather than the active compound. Under such a construction, the term "about" informs one of ordinary skill in the art to select whatever quantity of the derivative compound necessary to give exactly 35 (or 70) mg of alendronic acid; for alendronate monosodium trihydrate, the word "about" thus meant that 45.68 mg (or 91.35 mg) of that compound should be delivered - the amount necessary to give exactly 35 (or 70) mg of alendronic acid.

Unlike the limiting definition of "about" adopted by the district court, Teva's interpretation of the paragraph in question would mean that "70 [or 35] mg" refers to the amount of the active compound to be administered rather than the amount of the derivative compound. The term "about" in the claims would then serve to modify the quantity of the active compound in a way consistent with its normal definition of "approximately." Under this construction, the

modifying phrase "about 70 [or 35] mg" would refer to approximately 70 (or 35) mg of alendronic acid.[8]

The claim construction urged by Merck and adopted by the district court reads the sentence of the passage underlined above out of context. In the sentence before the highlighted sentence, the patentee informs those of ordinary skill in the art that, when the patent refers to a certain amount of a bisphosphonate compound, it is actually instructing them to administer a certain amount of the active component of the compound rather than the compound itself, i.e., that one should calculate the amount dispensed on an "active weight basis." This preceding sentence thus acts to specify a common denominator to be used for all derivatives of alendronic acid. The underlined sentence merely gives a specific example - that of an alendronate derivative - to show what is meant by using the phrase "active weight basis."

Given that the passage that Merck relies on is amenable to a second (and more reasonable) interpretation, we hold Merck did not clearly set out its own definition of "about" with "reasonable clarity, deliberateness, and precision," and thus failed to act as its own lexicographer. In re Paulsen, 30 F.3d at 1480.

As further support for this conclusion, we note that other parts of the specification also suggest that "about" should be given its ordinary meaning of "approximately." The specification repeatedly describes a range of acceptable

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[8] Merck argues that the district court's construction is supported by the fact that "about" was not used twice in the underlined sentence cited by Merck, i.e., that the specification does not state that "the amount of bisphosphonate compound selected is calculated based on about 70 mg of alendronic acid." (emphasis added). While Merck's grammatical savvy is noted, we believe that the omission of a second "about" is likely an inadvertent error rather than the product of meticulous drafting.

dosage amounts, with the patentee emphasizing that unit dosages will vary. For example, the specification suggests that a once-weekly dosage amount could contain anywhere from about 17.5 mg to about 70 mg of any alendronate compound on an alendronate acid active basis, with about 35 mg and about 70 mg being only two examples of a unit dosage:

> For once-weekly dosing, an oral unit dosage comprises from about 17.5 mg to about 70 mg of the alendronate compound, on an alendronic acid active weight basis. Examples of weekly oral dosages include a unit dosage which is useful for osteoporosis prevention comprising about 35 mg of the alendronate compound, and a unit dosage which is useful for treating osteoporosis comprising about 70 mg of the alendronate compound.

'329 patent, col. 12, II. 56-63 (emphasis added). In addition to the above passage, at another point in the specification the range for the normal unit dosage is further widened to "about 8.75 to about 140 mg." '329 patent, col. 12, II. 52-55 (stating that "a unit dosage typically comprises from about 8.75 mg to about 140 mg of an alendronate compound on an alendronic acid active weight basis"). The specification thus suggests the patentee contemplated a range of dosages, further compromising Merck's proposition that it acted as its own lexicographer in defining "about" to mean "exactly."[9]

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[9] We also note that Examples 7 and 8 in the '329 patent do not contradict the construction we adopt on appeal because they are only examples of the tablets that could be prepared according to the patent. Neither example clearly states that the only embodiment of the claims would be the exact formulations described therein.

Finally, our construction of "about" eliminates the problem pointed out by Teva that the district court's construction of the term "about" renders other parts of the claim superfluous. As Teva notes, the specification uses both the term "about" and "on an alendronic acid basis" at least 15 times to describe a dosage strength. If, as Merck urges, "about 35 [or 70] mg" means exactly 35 (or 70) mg of alendronic acid, then the oft-repeated phrase "on an alendronic acid active basis" would be unnecessary since such an understanding would be clear simply by using the term "about." A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so. Elekta, 214 F.3d at 1307 (construing claim to avoid rendering the 30 degree claim limitation superfluous); Gen. Am. Transp. Corp. v. Cryo-Trans, Inc., 93 F.3d 766, 770 (Fed. Cir. 1996) (rejecting the district court's claim construction because it rendered superfluous the claim requirement for openings adjacent to the end walls). By construing "about" to mean its accepted and ordinary meaning of "approximately," the phrase "alendronic acid basis" is no longer excess verbiage, but is instead necessary because it is the noun that "about 35 [or 70] mg" modifies.

Because the patentee did not clearly redefine "about" in the specification, and because the district court construed the claim term in a manner inconsistent with the specification, we reverse the district court's claim construction. We thus hold that the term "about" should be given its ordinary and accepted meaning of "approximately."

C. Invalidity

In light of the corrected claim construction we find reversible error in the district court's obviousness analysis. A patent claim is invalid "if the differences between the subject matter sought to be patented and the prior art are such that

the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (2000). The ultimate issue of obviousness turns on four factual determinations: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of nonobviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). As explained below, we find clear error in the trial court's findings on these underlying facts.[10] On reviewing these factual bases, we conclude the district court also erred in refusing to invalidate claims 23 and 37 for obviousness in view of the 1996 Lunar News articles.

The central issue concerns the differences between the aspects of the invention claimed at claims 23 and 37, and the teachings of the Lunar News articles. As the district court necessarily recognized, there are more similarities than differences. These claims, and the July 1996 article, both teach administering alendronate once a week instead of once a day. These claims read in light of the specification, and the July 1996 article, both indicate - and it has been conceded as known in the art at the time[11] - that for treating or preventing osteoporosis a once-weekly dosage at seven times the daily dose would be as effective as seven daily doses. The '329 patent, and both the April and July 1996 articles, explain the motivation for a once-weekly dose as increasing patient compliance, by making it easier to take the drug (and incur

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[10] It makes no difference to this conclusion whether the court begins with the claim construction set forth by the panel or the dissent. In either case, the district court erred in finding the '329 patent was not invalid as obvious in view of the Lunar News articles.

[11] See Merck, 288 F. Supp. 2d at 624.

the inconvenience of the rigorous dosing regimen less frequently). Although the claims teach 70 or 35 mg doses rather than the 80 or 40 mg doses disclosed in the July 1996 article, Dr. Arthur C. Santora - one of the co-inventors on the '329 patent - admitted against Merck's interest that a once-weekly 40 mg dose would be as effective as seven daily 5 mg doses, and a once-weekly 80 mg dose would be as effective as seven daily 10 mg doses, in preventing or treating osteoporosis. There was no great leap required of those skilled in the art to go from 40 or 80 mg once a week, the pills available at the time to treat patients with Paget's disease, to a 35 or 70 mg pill once a week. The district court's conclusion that the claims are not obvious cannot rest on any of these similarities between the claimed invention and the two Lunar News articles.

The district court distinguished the two Lunar News articles on grounds that they failed to explain how the once-weekly dosing overcame concerns in the art with adverse GI side effects. Merck, 288 F. Supp. 2d at 628-29. We are left with the firm conviction that this distinction is misplaced. As noted, the district court found those in the art had identified two types of adverse GI problems with alendronate. The first, and most significant, involved esophageal injury or repetitive irritation of the esophagus. The district court, reviewing the October 1996 article by DeGroen in the New England Journal of Medicine, expressly recognized the literature taught that complications related to alendronate were due to "prolonged contact of the drug with the esophagus." Merck, 288 F. Supp. 2d at 627. Confronted with this problem, Merck revised its dosing instructions and sent the clarifying materials to prescribing physicians in a March 1996 "Dear Doctor" letter. After Merck sent this letter, the reported incidence of GI distress fell to almost nothing even as the number of patients being prescribed Fosamax doubled by October 1996. Although the '329 patent focuses on this

adverse GI side-effect, it provides no additional motivation to overcome this problem beyond the motivation described in the two articles. The '329 patent, both articles, and the prevailing knowledge of those skilled in the art, recognized that to the extent "dosing problems" were related to repetitive irritation of the esophagus (from patients getting pills stuck in their throats), taking fewer pills each week could reduce the attending GI problems.[12] Thus, the district court clearly erred in finding any significant difference between the claimed invention and the two articles as to this type of GI problem.

The district court found a second adverse GI side-effect related to the size of the dose, which Merck argued gave rise to "the expectation by physicians in the field during 1996-1997 that alendronate sodium at doses over 20 mg would not be well-tolerated in the prevention and treatment of osteoporosis." Merck, 288 F. Supp. 2d at 624; see also id. at 622-23, 627-30 (discussing Chesnut study). Neither the '329 patent nor the Lunar News articles explain how a higher

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[12] As the '329 patent states:

> [I]t is found that the administration of a biphosphonate at a high relative dosage at a low relative dosing frequency causes less adverse gastrointestinal effects, particularly esophageal effects, compared to the administration of a low relative dosage at a high relative dosing frequency.
> ... Such administration methods of the present invention would be especially beneficial in treating patients that have been identified as suffering from or are susceptible to upper gastrointestinal disorders, e.g., gastrointestinal reflux disease (i.e. "GERD"), esophagitis, dyspepsia (i.e. heartburn), ulcers, and other related disorders. In such patients conventional bisphosphonate therapy could potentially exacerbate or induce such upper gastrointestinal disorders.

'329 patent, col. 3, l. 57 - col. 4, l. 13 (emphasis added).

once-weekly dosing regimen would avoid this set of dose-related adverse side effects. The '329 patent sets forth no human clinical or laboratory data showing the safety and tolerability of the treatment methods claimed by the patent. The only data provided in the '329 patent was generated in beagles, an experiment discredited at trial and disregarded by the district court in its decision. So while the district court may be correct in finding the Lunar News articles may have invited skepticism based on concerns for dose-related GI problems, the claimed invention adds nothing beyond the teachings of those articles. Thus, the district court clearly erred in finding any difference between the claimed invention and the articles on this point.

The district court's only remaining distinction between the claimed invention and the two Lunar News articles goes to the probative value of the articles. The trial court wrote that it "[was] not persuaded that the two Lunar News articles, not published in peer-reviewed journals or authored by one skilled in the art, either alone or in combination, overcame the serious side effect concerns associated with higher dosage units of alendronate sodium." Merck, 288 F. Supp. 2d at 629. Although these indicia of reliability - whether a study is peer-reviewed, and the credentials of the author - properly go to weight when the trial court has not excluded evidence as unreliable and irrelevant, the district court's reliance on these factors to distinguish Merck's claimed invention is, again, misplaced. First, as noted above, these factors provide no relevant distinction between the articles and the claimed invention because the '329 patent also fails to explain how its higher dosing would overcome these dose-related side-effects. Second, as explained below the district court's finding the author of the Lunar News articles not skilled in the relevant art is inconsistent with the court's own definition of the relevant art. Thus, the extent to which the district court

discounts the probative value of the two articles based on the credentials of the author calls for closer scrutiny and casts doubt on the findings that depend on this reasoning.

In short, the district court clearly erred in distinguishing the claimed invention from the two Lunar News articles offered as section 103 prior art. Contrary to the district court's findings, these articles support the conclusion that Merck's claims 23 and 37 are invalid as obvious.

For similar reasons we find the district court's characterization of the scope and content of the prior art favors invalidating claims 23 and 37 as obvious. The district court described its larger task as identifying "a showing of the teaching or motivation to combine prior art references." Merck, 288 F. Supp. 2d at 625 (quoting In re Gartside, 203 F.3d 1305, 1319 (Fed. Cir. 2000)). But as shown above, in this case the Lunar News articles contain the relevant teaching of the weekly dosing claimed in the '329 patent. The "specific combination" of elements in claims 23 and 37 differs from the disclosure in the Lunar News articles only in terms of a minor difference in the dosage; without this difference, the Lunar News articles would anticipate claims 23 and 37 under section 102. For the Lunar News articles to render claims 23 and 37 obvious, the district court need only have found a suggestion or motivation to modify the dosages from those in the articles to those in the claims. See, e.g., Sibia Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1356 (Fed. Cir. 2000). But as noted above, Merck's own inventors admit the difference in dosing amount is obvious. If anything, concern over dosing amount suggests lowering the weekly dosage - from 80 to 70 mg, and from 40 to 35 mg, just as Merck did. The district court thus clearly erred to the extent it found lacking any motivation to combine existing knowledge with the Lunar News articles to reach the claimed invention.

The district court failed to ascertain the required motivation to combine references to achieve the claimed invention, and it ignored the plain teachings of the Lunar News articles. As the court stated, "the issue is when viewing the mosaic of prior art, whether those of ordinary skill in the art would have had the motivation to formulate a once-weekly seven-fold daily dose of alendronate, despite safety concerns." Merck, 288 F. Supp. 2d at 626.

The Lunar News articles had clearly suggested the once-weekly dosing. They did so, as noted above, and as described in the '329 patent, to avoid or minimize problems related to dosing frequency. And as shown above, the district court itself found this particular set of problems were of greatest concern in the art. Indeed, to the extent the district court finds Merck's weekly-dosing idea non-obvious because it went against prevailing wisdom, the court must still explain why Merck and not Dr. Mazess should get credit for the idea. Because Merck's idea added nothing to what came before, the district court's answer comes down to nothing more than the credentials of the authors. In this case that difference is not enough to avoid invalidating the claims.[13]

The district court answered its own question incorrectly, because its analysis of the prior art fails to credit its own distinction between the "safety concerns" from dosing frequency and dosing amount. As noted above, the claimed invention does not address the problems with the dosing amount, but only the more widespread problems of

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[13] Although the court is unsure whether an obviousness ruling can ever turn solely on the credentials of the inventors and prior art authors, where the prior art has been admitted, it need not decide that question here. As noted below, by the district court's own functional definition (if not its actual finding) Dr. Mazess was one of skill in the art, and the Lunar News was widely circulated in the field.

the dosing frequency. The court's review of the scope and content of the prior art itself focuses on this concern with "prolonged contact of the drug with the esophagus." Merck, 288 F. Supp. 2d at 627. This understanding of the prior art does not support a conclusion that the claimed invention as a whole was non-obvious in view of the prior art. See Para-Ordnance Mfg. v. SGS Imports Int'l Inc., 73 F.3d 1085, 1087; In re Kaslow, 707 F.2d 1366, 1374 (Fed. Cir. 1983). Insofar as the district court relied on safety concerns related to dosing frequency, the prior art favors the conclusion that taking pills once a week was obvious.

Thus, the scope and content of the prior art confirms that the invention claimed in claims 23 and 37 would have been obvious in view of the Lunar News articles. To the extent the district court interpreted the scope of the prior art otherwise, that was clear error.

We likewise find clear error in the district court's conclusion that Dr. Mazess was not skilled in the relevant art. The district court failed to credit the evidence showing Mazess's Lunar News was widely distributed among those working in the field of osteoporosis. Moreover, while we recognize the importance academic or professional training plays in establishing expert qualifications or the probative value of a section 103 reference, we think the district court failed to give proper credit to the fact that Dr. Mazess was an expert in osteoporosis. In focusing on Dr. Mazess's academic training, the district court ignored its own finding that one of skill in the art would be someone "working in the field of, or doing research on, osteoporosis." Thus, the district court erred in dismissing or minimizing the probative value of the Lunar News articles.

Finally, the district court erred in its weighing of secondary considerations of non-obviousness. Although the

district court correctly found Merck's once-weekly dosing of Fosamax was commercially successful, in this context that fact has minimal probative value on the issue of obviousness. Merck, 288 F. Supp. 2d at 629-30. Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art. Thus, the law deems evidence of (1) commercial success, and (2) some causal relation or "nexus" between an invention and commercial success of a product embodying that invention, probative of whether an invention was non-obvious. See Graham, 383 U.S. at 17-18 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."); McNeil-PPC, Inc. v. L. Perrigo Co., 337 F.3d 1362, 1370 (Fed. Cir. 2003).

That rationale has no force in this case. In Graham the Supreme Court relied on the reasoning from a law review note discussing commercial success. See Graham, 383 U.S. at 17-18, citing Note, Subtests of Nonobviousness": A Nontechnical Approach to Patent Validity, 112 U. Pa. L. Rev. 1169, 1175 (1964). The article suggested "[t]he possibility of market success attendant upon the solution of an existing problem may induce innovators to attempt a solution. If in fact a product attains a high degree of commercial success, there is a basis for inferring that such attempts have been made and have failed." As our predecessor court explained in In re Fielder, 471 F.2d 640, 644 (C.C.P.A. 1973), "[t]hese rationales, presumably approved by the [Supreme] Court, tie commercial success and the like directly to the practical, financial source of impetus for research and development." But that chain of inferences fails on these facts. Although

commercial success might generally support a conclusion that Merck's claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the Lunar News articles. Financial success is not significantly probative of that question in this case because others were legally barred from commercially testing the Lunar News ideas. Dr. Mazess, for example, could not put his ideas to practice in 1996 - he could only exhort Merck to try it. They did.

In this case Merck had a right to exclude others from practicing the weekly-dosing of alendronate specified in claims 23 and 37, given (1) another patent covering the administration of alendronate sodium to treat osteoporosis, U.S. Pat. No. 4,621,077 (issued Nov. 4, 1986); and (2) its exclusive statutory right, in conjunction with FDA marketing approvals, to offer Fosamax at any dosage for the next five years. 21 U.S.C. § 355(c)(3)(D)(ii) (2000). Because market entry by others was precluded on those bases, the inference of non-obviousness of weekly-dosing, from evidence of commercial success, is weak. Although commercial success may have probative value for finding non-obviousness of Merck's weekly-dosing regimen in some context, it is not enough to show the claims at bar are patentably distinct from the weekly-dosing ideas in the Lunar News articles. Thus, we conclude the district court misjudged this factor as confirming its conclusion of non-obviousness.

In short, we find the relevant Graham factors establish claims 23 and 37 of the '329 patent are obvious in view of the April 1996 and July 1996 Lunar News articles. Thus, we reverse the district court and hold claims 23 and 37 invalid.

III. CONCLUSION

We reverse the district court's claim construction and hold that "about" should be construed consistently with its ordinary meaning of "approximately." In addition, we vacate the district court's determination that the '329 patent was not invalid as obvious. We hold claims 23 and 37 invalid as obvious and not infringed. The district court's judgment of infringement is therefore

REVERSED

COSTS

A. No costs.

United States Court of Appeals for the Federal Circuit

04-1005

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

RADER, Circuit Judge, dissenting.

This case shows the consequences of paying only lip service to the often-cited, but rarely-followed lexicographer rule and the basic jurisprudential principle of according trial courts proper deference.

Elect the Lexicographer Option at Your Own Risk

With this court's claim constructions wavering between the plain meaning rule (often a subtle way for judges to impose their own semantic subjectivity on claim terms, see, e.g., K-2 v. Salomon, 191 F.3d 1356 (Fed. Cir. 1999) ("permanent" affixation of the wheels to the skate boot in the context of in-line skates did not include a bolt that could only be reached by tearing apart the shoe)) and the "specification über alles" rule (often a way for judges to import limitations not included in the claim, see, e.g., Phillips v. AWH Corp., 363 F.3d 1207, 1213-14 (Fed. Cir. 2004), vacated, reh'g en banc granted, 376 F.3d 1382 (Fed. Cir. July 21, 2004)), a patent applicant might suppose that the best option to define the scope of the claim language might be the lexicographer rule. Under the lexicographer rule, an inventor acts as an

independent lexicographer and can even give claim terms a meaning "inconsistent with its ordinary meaning." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003) (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325-26 (Fed. Cir. 2002)); see also Teleflex, 299 F.3d at 1325 ("[A]n inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.'" (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994))). Indeed, this court often acknowledges that an applicant, acting as a lexicographer, may define "black" as "white." See Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1563 (Fed. Cir. 1990) ("It is a well-established axiom in patent law that a patentee is free to be his or her own lexicographer and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings."); see also, e.g., Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1373 (Fed. Cir. 2004) (patentee defining "annular," which ordinarily means in the shape of a ring, to describe structures that are not circular or curved, but polygonal). In this case, the patentee used the lexicographer rule to define a lengthy phrase. In its definition, the patentee defined the phrase with precise values. The patentee's definition, however, fell five letters short of success because the phrase included the word "about." This court seized on that word, gave it an ordinary meaning, and cast aside the lexicographer rule without a convincing explanation. Moreover, this court overturned the result of a lengthy district court trial for the sole reason that the trial court applied this court's lexicographer rule. I find it hard to explain to the district court how it erred by following this court's rules.

The disputed term in claim 23 of the '329 patent is the phrase "about 70 mg of alendronate monosodium trihydrate.

on an alendronic acid basis." Similarly, the disputed term in claim 37 is the phrase "about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis." Teva contends that this court should parse out one word in that phrase, "about," and accord that single word its ordinary meaning of "approximately." Merck, on the other hand, contends that the term "about" is inseparable from the entire phrase, which it defines under the lexicographer rule to account for the variability in the active ingredient weight that would result from the use of a salt of alendronic acid.

The specification shows the proper interpretation of the disputed phrase. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."). In the specification of the '329 patent, the patentee exercised the lexicographer option and defined the disputed phrase as follows:

> Because of the mixed nomenclature currently in use by those o[f] ordinary skill in the art, reference to a specific weight or percentage of a bisphosphonate compound in the present invention is on an acid active weight basis, unless otherwise indicated herein. For example, the phrase "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis" means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

'329 patent, col. 10, l. 65 - col. 11, l. 8.

In a passage that classically invokes this court's lexicographer doctrine, the patentee clearly, deliberately, and precisely defined the phrase "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis." The patentee set forth that entire term with quotations, including the word "about" and then stated unambiguously that the "phrase . . . means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid." '329 patent, col. 11, ll. 2 - 8 (emphases added). The choice of the words "phrase" and "means," combined with the use of quotation marks to set the phrase off from the rest of the sentence, unmistakably notify a reader of the patent that the patentee exercised the option to define the entire phrase without respect to its ordinary meaning as understood by one of ordinary skill in the art at the time of the invention. See Multiform Dessicants Inc. v. Medzam Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

To underscore the choice to define the phrase as a lexicographer, the patentee explains the reason that this phrase needs definition - "[b]ecause of the mixed nomenclature currently in use by those o[f] ordinary skill in the art." '329 patent, col. 10, ll. 65-66. Therefore, even a casual reader, let alone one with skill in this art, would immediately recognize that the patentee intended to avoid any ambiguity inherent in "mixed nomenclature" by explicitly defining the entire phrase. See Paulsen, 30 F.3d at 1480 ("'Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change." (quoting Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388 (Fed. Cir. 1992))).

The language of this definition explains further the scientific reason that an express definition is necessary. Alendronate monosodium trihydrate is a bisphosphonate selected from the group consisting of alendronic acid, pharmaceutically acceptable salts thereof, and mixtures thereof. A salt or a mixture may require a different weight to achieve the same number of bisphosphonate molecules present in 70 mg of alendronate.

The patentee did not leave this difference vague, however, but instructed that the precise dose in claim 23 - "about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis" - means that the amount of alendronate monosodium trihydrate is calculated based on 70 mg of alendronic acid. Similarly, the disputed language of claim 37 - "about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis" - means that the amount of alendronate monosodium trihydrate is calculated based on 35 mg of alendronic acid. The word "about" in the defined phrase takes into account the variability of the weight of the active ingredient that would result from using different salts of alendronic acid in the tablets, instead of the acid itself. In other words, a heavier salt would require more by weight to achieve the same number of alendronate molecules. For example, about 70 mg of alendronate sodium, on an alendronic acid active basis, contains the same number of molecules of alendronate as 70 mg of alendronic acid, regardless of the actual weight of the alendronate sodium in the tablet.

With respect to the word "about," the patentee included that word in the entire phrase expressly defined in the specification and set off by quotation marks. Therefore, this court cannot, without disturbing the patentee's express definition of the entire phrase, abstract that term out of its context and supply an ordinary meaning. Thus, by abstracting

"about" out of the patentee's express definition, this court's opinion defeats the patentee's choice of words, punctuation, and phraseology and instead extracts a single word from its context in the phrase. Accordingly, the majority rewrites the express definition either by moving the word "about" outside of the quotation marks of the defined phrase or by inserting the word "about" into the definitional portion of the sentence so that it would read "the amount of the bisphosphonate compound is calculated based on about 70 mg of alendronic acid." If the patentee had chosen either of those two phraseologies, the majority opinion might be correct in its analysis. But because the patentee did not, this court cannot give any principled reason that the district court erred in applying the lexicographer rule. Contrary to this court's rules, this opinion rewrites the specification and substitutes language not chosen by the patentee. See, e.g., Chef Am., Inc. v. Lamb Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004) (repeating the well-established rule that "courts may not redraft claims").

Throughout the patent, the applicant remained faithful to the disputed phrases in claims 23 and 37 consistent with the specified lexicography, thus completely dispelling any notion of ambiguity in the term "about." In particular, Examples 7 and 8 corroborate the express definition. Example 7 states that "[t]ablets containing about 35 mg of alendronate, on an alendronic acid active basis, are prepared using the following weights of ingredients" and lists alendronate monosodium trihydrate requiring a mass of 45.68 mg. See '329 patent, col. 19, ll. 14 - 21. Similarly, example 8 states that "[a] liquid formulation containing about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis, per about 75 mL of liquid is prepared using the following weights of ingredients" and lists alendronate monosodium trihydrate having a mass of 91.35 mg. Id. at col. 19, ll. 44 - 52. In these examples, the applicant supplied an

exact weight that equates with "about 70 mg of alendronate . . . on an alendronic acid active basis." Accordingly, the district court did not err in construing "the disputed claim terms 'about 70/35 mg' to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories." Merck, 288 F. Supp. 2d at 616. The district court followed this court's rules.

Deference to Trial Courts:
Time for "Truth in Advertising?"

This is the classic "close case," so close in fact that ultimately two federal judges (one of whom conducted an entire bench trial on this issue) and the United States Patent and Trademark Office agreed with Merck & Co., and two federal judges agreed with Teva Pharmaceuticals. The United States District Court of Delaware tried this case from March 4 - 7, 2003, then issued a 75-page opinion analyzing the claims and arguments in consummate and accurate detail. Merck & Co. v. Teva Pharms. USA, Inc., 288 F. Supp. 2d 601 (D. Del. 2003). This court received the typical briefs from the parties, an appendix containing selected portions of the record, and heard a total of approximately thirty minutes of argument by the parties on the issues before this court. Despite the district court's superior tools and time to evaluate the complete record, to hear and inquire from expert and fact witnesses, to delve into countless related details, to probe the scientific and semantic context, and to entertain argument as long as necessary for clarity, this court with its reading three briefs before its half-hour hearing becomes enamored with its own analysis of a very close issue and reverses the district court.

This court often hears criticism from district court judges that its reversal rate on claim construction issues far

exceeds that of other circuit courts. See, e.g., Symposium, The Law, Technology and the Future of the Federal Circuit: A Panel Discussion: Claim Construction from the Perspective of the District Judge, 54 Case W. Res. L. Rev. 671 (2003) (Symposium I) (district judges discussing problems with this court's high reversal rate on claim construction issues); see Gregory J. Wallace, Note, Toward Certainty and Uniformity in Patent Infringement Cases after Festo and Markman: A Proposal for a Specialized Patent Trial Court with a Rule of Greater Deference, 77 S. Cal. L. Rev. 1383, 1391 (2004) (discussing various studies regarding this court's reversal rate on claim construction issues). In response, nearly every judge on this court has publicly professed to accord some level of deference to district courts regardless of this court's de novo review of claim construction issues. See, e.g., Symposium I at 680 (a district court judge stating "I have certainly heard a number of federal circuit judges agree, that the CAFC gives some deference to a well-reasoned opinion, as a practical matter"); Symposium, The Past, Present and Future of the Federal Circuit: Judicial Constellations: Guiding Principles as Navigational Aids, 54 Case W. Res. L. Rev. 757, 761 (2004)(judge of the Federal Circuit stating: "Review is really not de novo after all. It is unfortunate that there is no label in between de novo and clear error review. Functionally, claim construction falls in this middle ground."). Either the Federal Circuit accords deference in accordance with its public protestations or it does not in accordance with its legal standard barring any deference. If the former, this court has a "truth in advertising" problem. Its actual practice clashes with its professed legal duty. If the latter, this court has a different kind of "truth in advertising" problem.

In this case, this court eschews all deference, a particularly striking choice in the face of a very close case and a district court whose diligent and intelligent process and resolution earned more respect than it received. I am not

entirely sure which aspect of the "truth in advertising" problem this case illustrates, but it certainly makes any protestations of deference in fact sound rather hollow.

APPENDIX B

United States Court of Appeals for the Federal Circuit

04-1005

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, CLEVENGER, RADER, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.

ORDER

A combined petition for panel rehearing and rehearing en banc was filed by the Appellee, and a response thereto was invited by the court and filed by the Appellant.[1]

[1] An amicus curiae brief was filed by the Pharmaceutical Research and Manufacturers of America.

The petition for rehearing was referred first to the merits panel that heard the appeal. Thereafter, the petition for rehearing en banc, response, and the amicus curiae brief were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

(2) The petition for rehearing en banc is denied.

(3) The mandate of the court will issue on April 28, 2005.

NEWMAN and LOURIE, Circuit Judges, would rehear the appeal en banc.

LOURIE, Circuit Judge, with whom MICHEL, Chief Judge, and NEWMAN, Circuit Judge, join, dissents in a separate opinion.

SCHALL, Circuit Judge, did not participate in the vote.

FOR THE COURT

APR 21 2005
Date

Jan Horbaly
Clerk

cc: John F. Lynch, Esq.
James Galbraith, Esq.
William F. Lee, Esq.

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

Apr 21, 2005

JAN HORBALY
CLERK

United States Court of Appeals for the Federal Circuit

04-1005

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

LOURIE, Circuit Judge, with whom MICHEL, Chief Judge, and NEWMAN, Circuit Judge, join, dissenting from order denying rehearing en banc.

I respectfully dissent from the court's declining to hear this case en banc. In my opinion, the panel erroneously concludes that commercial success is not probative because "others were legally barred" from commercially testing certain ideas in the prior art. Moreover, I believe the panel erred in linking commercial success to the failure of others.

Commercial success is a fact question, and, once it is established, as found here by the trial court, the only other question is whether the success is attributable to the claimed invention ("nexus"), rather than to other factors such as market power, advertising, demand for all products of a given type, a rising economy that "lifts all boats," etc. It is not negatived by any inability of others to test various formulations because of the existence of another patent. Success is success. The panel's rule is especially unsound in the context of an improvement patent, as here, because it

holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention.

Commercial success is also independent of any "failure of others," as that is another, separate secondary consideration.

Respectfully, the full court should have reheard the appeal to eliminate the confusion in the law that the panel opinion creates.

APPENDIX C

FILED
Sep 24 9$_{43}$ AM '03
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant.

C.A. No. 01-0048 (JJF)
(CONSOLIDATED)

FINAL JUDGEMENT ORDER
PURSUANT TO FED. R. CIV. P. 54(b)

For the reasons set forth in this Court's Memorandum Opinion of August 28, 2003;

IT IS HEREBY ORDERED that:

1. Claims 23 and 37 of US. Patent No. 5,994,329 ("the '329 Patent") are not invalid;

2. The '329 Patent is not unenforceable;

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any Food and Drug Administration approval of Defendant's Abbreviated New Drug Application No. 75-710 with respect to tablets containing 70 mg or 35 mg of alendronate sodium (on an alendronic acid basis) for

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treatment or prevention of osteoporosis, respectively, will be a date not earlier than July 17, 2018, the expiration date of the '329 Patent;

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Defendant, its officers, agents, attorneys and employees, and those persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from engaging in the commercial use, offer to sell, or sale within the United States, or importation into the United States, of tablets containing 70 mg or 35 mg of alendronate sodium (on an alendronic acid basis) for the treatment or prevention of osteoporosis, respectively, on or before July 17, 2018, the expiration date of the '329 Patent;

5. Judgment is entered in favor of Plaintiff and against Defendant on Plaintiff's claims of infringement of claims 23 and 37 of the '329 Patent and on Defendant's defenses to those claims, and in favor of Plaintiff and against Defendant on Defendant's counterclaim relating to the unenforceability of the '329 Patent; and

6. On December 2, 2002, the Court entered a Final Judgment Order in Consolidated Actions C.A. No. 00-035-JJF and C.A. No. 00-052-JJF regarding U.S. Patent No. 4,621,077 (the "'077 patent"). The Court entered Judgment that Teva's filing of its Abbreviated New Drug Application No. 75-710 infringed claim 1 of the '077 patent, that the '077 patent is not invalid, and that the patent term extension of the '077 patent is valid. Teva appealed the Court's Final Judgment Order to the United States Court of Appeals for the Federal Circuit, and the appeal is pending. Per the parties' agreement, and Court's Order of March 7, 2003, the outcome of the appeal (and any subsequent proceedings) will be dispositive of all issues regarding Merck's infringement

claims and Teva's counterclaims brought in this action regarding the '077 patent.

Accordingly, in accordance with Fed. R. Civ. P. 54(b), there is no just reason for delay in entering this Judgment and the Court directs that it be entered.

SO ORDERED this 23 day of September, 2003.

United States District Judge

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DISTRICT OF DELAWARE
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APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,
Plaintiff,
v.
TEVA PHARMACEUTICALS USA, INC.,
Defendant.

Civil Action No. 01-048 (JJ
(Consolidated)

Mary B. Graham and Maryellen Noreika, Esquires of MORRIS, NICHOLS, ARSHT & TUNNELL, Wilmington, Delaware.
Of Counsel: John F. Lynch, Nicolas G. Barzoukas, and Stephen E. Edwards, Esquires of HOWREY SIMON ARNOLD & WHITE, LLP, Houston, Texas.
Paul D. Matukaitis, Edward W. Murray, and Gerald M. Devlin, Jr. Esquires of MERCK & CO., Whitehouse Station, New Jersey.
Attorneys for the Plaintiff.

Josy W. Ingersoll, and Adam W. Poff Esquires of YOUNG, CONAWAY STARGATT & TAYLOR, LLP, Wilmington, Delaware.
Of Counsel: James Galbraith, Maria Luisa Palmese and William G. James, II, Esquires of KENYON & KENYON, New York, New York.
Attorneys for Defendant Teva Pharmaceuticals, USA, Inc.

OPINION

August 28, 2003
Wilmington, Delaware.

Farnan, District Judge.

I. **Procedural Background**

Plaintiff, Merck & Co., Inc. ("Merck") is a Delaware corporation with its principal place of business in New Jersey. Defendant, Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation with its principal place of business in Pennsylvania. Merck is the owner of the entire right, title and interest in United States Patent No. 5,994,329, entitled "Method for Inhibiting Bone Resorption" (the "'329 Patent"), which issued November 30, 1999, naming as inventors Anastasia G. Daifotis, Arthur C. Santora I, and John Yates. Merck filed the application for the '329 Patent on July 22, 1997. The '329 Patent is set to expire on August 14, 2018. (PTX 1).

Merck listed the '329 Patent in the Federal Drug Administration's ("FDA") publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in connection with its 70 mg and 35 mg dosage for alendronate sodium, which Merck markets under the name "Fosamax." On October 3, 2000, Teva filed a supplement to an existing Abbreviated New Drug Application ("ANDA") seeking FDA approval to market generic versions of Merck's 70 mg alendronate sodium product for weekly administration. Included with Teva's ANDA filing were "paragraph IV" certifications (21 U.S.C. § 355 (j) (2) (A) (vii) (IV)) asserting that the Patents listed in the Orange Book, including the '329 Patent, are invalid, unenforceable or would not be infringed by the commercial marketing of Teva's proposed product. Merck filed this action on January 21, 2001, alleging that Teva's filing of its supplement was an act of infringement under 35 U.S.C. § 271 (e) (2) (A). Thereafter, Merck listed U.S. Patent No. 6,225,294 (the "'294 Patent") in the Orange book and Teva

filed a paragraph IV certification asserting that the '294 Patent is invalid, unenforceable or would not be infringed by the commercial marketing of Teva's proposed 70 mg alendronate sodium product. On October 4, 2001, Merck filed Civil Action No. 01-675-JJF, alleging that Teva's filing of its supplemental ANDA was an act of infringement of the '294 Patent under 35 U.S.C. § 271 (e) (2) (A).

Subsequently, Teva filed another supplement to its ANDA, seeking approval to market a generic version of Merck's 35 mg Fosamax product. The supplement also included a paragraph IV certification asserting that all the listed patents were invalid, unenforceable or would not be infringed by Teva's commercial marketing of its proposed product. On November 6, 2001, Merck filed Civil Action No. 01-728, alleging that the filing of Teva's supplement to the ANDA was an act of infringement under 35 U.S.C. § 271 (e) (2) (A). On January 14, 2002, the Court consolidated all three cases under Civil Action No. 01-048.

One of the listed patents against which Teva certified was U.S. Patent No. 4,621,077 ("the '077 Patent"), which had already been the subject of litigation between the parties in this Court (Civil Action No. 00-035-JJF) in connection with Teva's application to market alendronate sodium for daily administration. The Court entered judgment in favor of Merck in that case on December 2, 2002, and an appeal from that judgment is now pending in the United States Court of Appeals for the Federal Circuit. (D.I. 123-1). The parties agreed that they will be bound in this case, with regard to issues concerning the '077 Patent, by a final decision in the prior litigation. (D.I. 128). Prior to trial Merck stipulated that the only claims at issue in this litigation are claims 23 and 37 of the '329 Patent and further stipulated that it would not allege an invention date for those claims prior to July 22, 1997. (D.I. 128).

Teva stipulated that if found valid and enforceable, claims 23 and 37 of the '329 Patent would be infringed by the commercial marketing of Teva's proposed 70 mg and 35 mg alendronate sodium products for weekly administration. (D.I. 109, Pretrial Order, Tab 1, ¶¶ 8-9). The issues of validity and enforceability of the '329 Patent were tried before the Court from March 4-7, 2003.

The Court has jurisdiction over the parties and the subject matter pursuant to 28 U.S.C. § 1338(a). Additionally, venue is appropriate under 28 U.S.C. § 1391(c) and § 1400(b). Neither jurisdiction nor venue are contested by the parties. This Opinion constitutes the Court's Findings of Fact and Conclusions of Law with respect to the issues tried before the Court.

II. The '329 Patent and Bone Biology In General

The '329 Patent discloses less-frequent-than daily administration of bisphosphonates (e.g., alendronate) to inhibit bone resorption. (D.I. 143 at 8). Claims 23 and 37, the only asserted claims, relate specifically to the treatment and prevention of osteoporosis by once-weekly administration of alendronate. Osteoporosis is related to processes that are imbalanced in bone, and therefore, the Court will discuss the background of bone biology as it relates to osteoporosis and the use of alendronate for treatment of the disease.

Bone is the tissue that provides mechanical support to the body. It is made up of a protein matrix, which is overlaid with mineral to give it hardness. (Russell[1] at 108-109; DTX 523 at 2). Two principal types of cells maintain bone: 1) osteoclasts, which break down bone, and 2) osteoblasts,

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[1] The bench trial transcript is cited throughout the Opinion by a notation to the witness and the page number of the transcript.

which build new bone. Id. The process of bone destruction and rebuilding is known as "remodeling." In the bone remodeling process, osteoclasts attach to the bone surface, become activated, and erode away the bone material beneath them, leaving defects in the bone structure. The destruction of bone by osteoclasts is called bone "resorption." Osteoblasts then attach to the eroded surface of these defects, lay down new bone, and then become inactive. In the normal healthy adult the remodeling process is balanced. In other words, bone is destroyed and built at the same rate. (Russell at 109-110; DTX 523 at 3-4).

In osteoporosis, bone destruction and formation are no longer balanced and bone is destroyed faster than it is replaced. Therefore, osteoporosis can lead to bone that is thinner, weaker, more fragile and porous. (Russell at 110-115; DTX 523 at 7, 8). Osteoporosis is treated primarily by inhibiting bone resorption - thus restoring the balance between bone destruction and formation. Alendronate inhibits bone resorption by blocking the bone destroying effects of osteoclasts. (Russell at 116-117). A small portion of the ingested drug makes its way to and adheres to the bone surface, where it resides until it is taken up by osteoclasts. The alendronate then inhibits the osteoclasts from resorbing bone. (Russell at 121-122; DTX 523 at 10).

Paget's disease is also a common bone disease characterized by increased bone resorption. In Paget's disease, increased bone remodeling occurs in localized areas of the skeleton. If Paget's disease is not detected and treated early it can lead to an increase in bone size, fractures, and deformity. (Russell at 97). Like osteoporosis, Paget's disease is treated by inhibiting bone resorption with alendronate. (Russell at 125-126).

III. Teva's Motion in Limine to Preclude Merck From Relitigating the Factual Findings Underlying the Decision in Teva Pharmaceuticals Ltd. et al. v. Instituto Gentili Spa et al. (D.I. 113).

Teva filed a Motion in Limine to Preclude Merck from Relitigating the Factual Findings Underlying the Decision in Teva Pharmaceuticals Ltd et al. Istituto Gentili Spa et al., (High Court of Justice, Chancery Division, Patents Court, January 21, 2003)). (D.I. 113). Accordingly, the Court will discuss the motion in limine before it delves into the issues of validity and enforceability of the '329 Patent.

Teva's principal defense in this case is that claims 23 and 37 are invalid because the claimed invention is anticipated or would have been obvious in view of the prior art. At the same time that the parties were litigating the validity of the '329 Patent in this Court, they were also involved in a case in the British High Court of Justice (the "High Court"). That case was a challenge by Teva and others to the validity of the European Patent No. 998,292 (the "'292 Patent"), which corresponds to the '329 Patent, and is based on the same provisional applications filed in July 1997. Teva, by its motion, contends that the '292 Patent covers the identical concept as the '329 Patent: the once-weekly dosing of alendronate sodium to treat osteoporosis, using seven times the normal daily dose.[2]

The High Court conducted a full trial on the merits from November 5-8, 2002, and heard further arguments from counsel on November 12-13, 2002. The trial involved live testimony from Merck's expert Dr. Socrates Papapoulos, who

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[2] This claim is in the form of a "Swiss claim." Such claims are used in attempts to avoid restrictions on claiming methods of treatment, which are unpatentable in many countries.

is Merck's expert in this case. In addition, Merck offered the testimony of Dr. Yates, the principal inventor of the '329 Patent, who also testified in this case. On January 22, 2003, Justice Jacob of the High Court found that the claimed invention was invalid because it would have been obvious to a person skilled in the art, it claims a method of treatment, and is incapable of industrial application.

A. Applicable Legal Principles

Teva contends that the Court should adopt the High Court's factual findings concerning obviousness pursuant to the doctrine of collateral estoppel. Collateral estoppel is appropriate if: (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) plaintiff had a full and fair opportunity to litigate the issue in the first action. Micron Technology, Inc. v. Rambus, Inc., 189 F. Supp. 2d 201, 209 (D. Del. 2002) (citations omitted). Additionally, the doctrine of collateral estoppel applies in patent cases. See Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation, 402 U.S. 313 (1971).

B. Parties' Contentions

1. Teva's Contentions

By its motion, Teva contends that Merck had the identical motivation in litigating the British case as it does in the instant case: to discredit the Lunar News (a prior art reference) and Teva's reliance on its teachings. Moreover, Teva contends that Merck's barristers were afforded a full and fair opportunity to cross-examine all of Teva's witnesses and did so at length. Teva contends that the evidence was heard by Justice Jacob of the High Court, who is experienced in patents.

On January 22, 2003, Justice Jacob found the '292 Patent invalid and entered judgment against Merck. In its motion, Teva concedes that the legal standard may vary between Britain and the United States; nevertheless, Teva contends that regardless of the differences, if any, between the legal standards for determining validity, collateral estoppel should still apply to the resolution of the underlying factual issues. Specifically, Teva contends that all of the elements of collateral estoppel are met in this case with regard to the High Court's factual findings on obviousness.

First, Teva contends that collateral estoppel applies to fact findings of foreign courts. Teva argues that courts have recently recognized that parties who litigate in a foreign court should be bound by the results of that litigation to the extent that the requirements of the collateral estoppel doctrine are met. For example, Teva points to Vas-Cath, Inc. v. Mahurkar, 745 F. Supp. 517 (N.D. Ill. 1990), rev'd on other grounds, 935 F.3d 1555 (Fed. Cir. 1991), where the parties extensively litigated the issue of obviousness in Canada, and the district court held that the parties were bound by the fact-finding of the Canadian Court. Additionally, Teva points to Northlake Marketing & Supply, Inc. v. Glaverbel, S.A., 958 F. Supp. 373, 379 (N.D. Ill. 1997) ("Northlake I") and Northlake Marketing & Supply, Inc. v. Glaverbel, S.A., 986 F. Supp. 471, 475-76 (N.D. Ill. 1997) ("Northlake II"), where the parties had previously litigated the validity of a Belgian patent that corresponded to the United States patent in suit. The district court in those cases held that the Belgian Court's conclusions about the scope and content of prior art were binding on the parties in the United States litigation.

Further, Teva directs the Court to Oneac Corp. v. Raychem Corp., 20 F. Supp. 2d 1233, 1242-1243 (N.D. Ill. 1998), where a corresponding European patent was litigated in the High Court and the district court held that with respect

to the United States patent, it would not give preclusive effect to questions of law or mixed questions of law and fact, but it would adopt the British Court's factual findings. Additionally, Teva points to Federal Circuit decisions that have declined to afford collateral estoppel effects to judgments in foreign cases, but distinguishes them on the basis that those decisions were predicated on what the Federal Circuit views as different standards of patentability in other countries. See, e.g., Meditronic Inc. v. Daig Corp., 789 F.2d 903 (Fed. Cir. 1996) (declining to adopt German tribunal's determination that corresponding German patent was invalid in view of different legal standards); In re Duhlberg, 472 F.2d 1394 (C.C.P.A. 1973) (same).

Second, Teva contends that the issues were the same in the British litigation; the obviousness of administering alendronate sodium once a week at a dose of about seven times the daily dose. Further, Teva argues that the issue of the scope and content of the prior art are the same in both cases; whether the Lunar News publications taught the administration of alendronate sodium once a week, and whether the prior art taught that the dose should approximate seven times the daily dose. In addition, Teva argues that Merck's fear defense is an issue in both cases. Merck claims that persons skilled in the art would have rejected the Lunar News teachings because of the fear that patients would not tolerate the larger dose. Merck raised the issue in Britain, and after considering the evidence, the High Court concluded that the "fear defense fails". For example, the High Court found that the rare instances of esophageal side effects were attributed primarily to failure to follow the dosing instructions (D.I. 114, Ex. A, ¶ 65).

Third, Teva argues that the same issues were actually litigated in the High Court. For instance, Teva contends, the parties fully aired all factual evidence, where both sides had

qualified expert witnesses to explain the evidence to the Court. Further, Teva argues that all witnesses appeared live and were extensively cross-examined and after the trial both parties provided written submissions and appeared for extensive argument before Justice Jacob. As a result, Teva argues, Merck cannot contend that these issues were not litigated.

Fourth, Teva argues that the issues were determined by a valid and final judgment. Teva points out that the judgment of the High Court was the "Approved Judgement of that Court." It was issued on January 21, 2003 and reissued in corrected form January 22, 2003. Teva notes that Merck has appealed the judgment, but that fact does not imply that the judgment is not final for purposes of collateral estoppel. In fact, Teva argues that it is well settled that the pendency of an appeal does not diminish the preclusive effect of an appealed judgment. (D.I. 114 at 13) (quoting Rice v. Department of Treasury, 998 F.2d 997, 999 (3d Cir. 1993)).

Lastly, Teva contends that the resolution of obviousness was essential to the judgment in the High Court. Specifically, it contends that Justice Jacobs was required to and did evaluate and interpret the prior art provided by Merck's witnesses, and that, all findings on these issues were necessary to his final judgment that the patent was invalid for obviousness. Based on this, Teva argues that the High Court's factual findings should be given preclusive effect.

2. Merck's Contentions

In response, Merck argues that there is no transnational collateral estoppel as to the validity of a United States Patent. First, Merck contends that Teva fails to point to a single Federal Circuit case where, a foreign court's judgment that the patent was invalid, or the factual underpinnings of such a judgment, was given collateral

estoppel effect in a case litigating the validity of a United States Patent. In fact, Merck argues that the Federal Circuit and its predecessor court have rejected such attempts. For example in Meditronic Inc. v. Daig Corp., 789 F.2d 903 (Fed Cir. 1986), cert. denied, 107 S. Ct. 402 (1986), the Federal Circuit rejected the argument that it should adopt the conclusion of a German tribunal that a German counterpart was obvious and stated, "[t]his argument is specious. The patent laws of the United States are the laws governing a determination of obviousness/nonobviousness of a United States patent in a federal court." Id. at 907-908.

Additionally, Merck contends that the predecessor to the Federal Circuit came to the same conclusion in In re Duhlberg 472 F.2d 1394, 1398 (C.C.P.A. 1973) and In re Larsen, 292 F.2d 531, 533 (C.C.P.A. 1961), where in both cases, the court refused to consider the actions of a foreign country's patent office with respect to the patentability of the subject matter before the court.

Further, Merck argues that district courts have refused to give collateral estoppel effect to a foreign court's judgment. For example, Merck points to Cuno, Inc. v. Pall Corp., 729 F. Supp. 234 (E.D.N.Y. 1989), where the High Court found the European counterpart of the United States patent at issue to be valid and infringed, and when the plaintiff sought to have the United States district court give collateral estoppel effect to certain factual findings, the court denied the request and stated. that:

> Even if the court were to apply collateral estoppel to certain factual findings made by the British Court - as opposed to importing its legal conclusions wholesale-it is not clear that the trial time would be significantly shortened. Furthermore, the Federal Circuit's reluctance to give collateral estoppel effect

> to foreign judgments would seem to apply here to foreign findings of facts insofar as those findings involve mixed questions of fact and foreign law.

Id. at 238-239.

Moreover, Merck distinguishes the cases cited by Teva. First, in regard to the Oneac case, Merck points out that the court refused to give preclusive effect to questions of law or mixed questions of law and fact, and to the extent that certain factual findings were given collateral estoppel effect, it was because both parties to the suit agreed to be bound by those factual determinations. Oneac Corp., 20 F. Supp. 2d at 1242-1243. Additionally, Merck points to the Vas-Cath case where the Northern District of Illinois adopted certain factual findings of a Canadian Court in regard to the validity of a patent, after parsing out the Canadian judgment, comparing the relative Canadian and United States' laws and making its own conclusions regarding the applicability of the factual determinations in the context of the United States' legal framework. Additionally, in the Northlake cases, Merck points out that the district court adopted only certain factual findings from a previous Belgian proceeding after careful review of those findings and contends that most importantly, the issues that were precluded limited the evidence that the patent challenger could rely on. See Northlake II, 986 F. Supp. 475-476; Northlake I, 958 F. Supp. at 379.

Next, Merck argues that the requirements for collateral estoppel have not been met. First, Merck contends that the High Court's factual findings regarding obviousness were not essential to the final judgment because the High Court found that the '292 was invalid based on three grounds: 1) invalid as a method of treatment; 2) incapable of industrial application; and 3) invalid as obvious- not obviousness alone.

Lastly, Merck argues that the facts and applicable legal standard is different. Specifically, Merck contends that in the United States obviousness is ultimately a question of law which rests on the following factual inquiries: 1) the scope and content of prior art; 2) the level of ordinary skill in the art; 3) the differences between the claimed invention and the prior art; and 4) objective considerations of nonobviousness. See Advanced Display Systems, Inc. v. Kent State Univ., 212 F.3d 1272, 1284-85 (Fed. Cir. 2000). On the other hand, Merck argues, in Britain, the determination of obviousness is based on the following factual inquiries: 1) identifying the inventive concept embodied in the patent in suit; 2) assuming the mantle of the normally skilled but unimaginative addressee in the art at the priority date and impute to him what was, at that date, common general knowledge in the art; 3) identifying what, if any, differences exist between the matter cited as being made available to the public and the alleged invention; 4) determining whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they required any degree of invention. (D.I. 126 at 17) (citing Windsurfing International, Inc. v. Tabur Marine (Great Britain) Ltd., 1985 R.P.C. 59, 60-61 (1985 Ct. Of Appeal)). Merck contends that although these standards are similar, the United States Court is required to consider objective considerations of obviousness, while in Britain they are not. Accordingly, Merck contends that collateral estoppel is improper.

C. **Discussion**

As outlined above, the standards for determining obviousness in the United States and Britain are different. In fact, for purposes of this motion, Teva concedes that there may be differences in the legal standards for validity between

the United States and Britain. Additionally, after reviewing the "factual findings" of the High Court, the Court finds that many of the principles are mixed questions of law and fact. The cases cited demonstrate that mixed questions of law and fact should not be adopted if there are two different legal standards, as in this case. See, e.g., Oneac Corp., 20 F. Supp. 2d at 1242-1243 (declining to adopt mixed questions of law and fact). Additionally, in Oneac the court only adopted factual findings from a foreign tribunal where the parties agreed to be bound by such factual findings. Id. at 1242-43. This is not the situation in the instant case because Merck opposes any adoption of the High Court's factual findings. Also, the Court finds that Merck has successfully distinguished the Northlake cases from the instant case, where in the Northlake cases the issues that were precluded limited the evidence that the patent challenger could rely on and the adopted factual findings did not go to the validity of the patent in suit.

The Court also concludes that all of the elements necessary for a finding of collateral estoppel are not present in this case. Specifically, the High Court's factual findings relating to obviousness were not essential to the High Court's decision because that decision was based on three separate grounds as detailed above. The Third Circuit has stated that "if a judgment of a court of first instance is based on determinations of two issues, either of which standing independently would be sufficient to support the result, the judgment is not conclusive with respect to either issue standing alone." Arab African Int'l Bank v. Epstein, 958 F.2d 532, 535, (3d Cir. 1992) (quoting Restatement (Second) of Judgments § 27, cmt. i), rev'd in part on other grounds, 10 F.3d 168 (3d Cir. 1996). The Court concludes that based on this standard, the High Court's finding of obviousness cannot be said to be essential to the final determination.

There may be cases where "the balance tips in favor of preclusion because of the fullness with which the issue was litigated and decided in the first action." Masco Corp v. United States, 303 F.3d 1329-1330 (Fed. Cir. 2002). However, the Court concludes that this is not such a case, especially in light of the fact that the Federal Circuit has cautioned courts against giving too much weight to foreign tribunals who are confronted with the same prior art. See Heidelberger Druckmaschinen AG v. Hantscho Comm. Prods., Inc., 21 F.3d 1068, 1072 (Fed. Cir. 1994) (recognizing that theories and laws of patentability differ from country to country and stating that "[c]aution is required when applying the action of a foreign patent examiner to deciding whether the requirements of 35 U.S.C. § 103 are met under United States law, for international uniformity in theory and practice has not been achieved."). While the Court has reviewed Justice Jacob's factual findings in regard to obviousness, based on the aforementioned reasons, the Court declines to adopt them and will make independent findings of fact on the issue of validity. Accordingly, Teva's motion will be denied.

IV. **Invalidity**

Once issued a patent is presumed to be valid. See 35 U.S.C. § 282. The party challenging the patent bears the burden of proving by clear and convincing evidence that the patent is invalid. See Helifix Ltd. v. Blok-Lok Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000). Clear and convincing evidence is evidence that places in the fact finder "an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" Colorado v. New Mexico, 467 U.S. 310, 316 (1984).

Defendants contend that the '329 Patent is invalid and therefore cannot be infringed. Defendants argue invalidity on

two grounds: anticipation by the July 1996 Lunar News reference under 35 U.S.C. § 102(e), and obviousness under 35 U.S.C. § 103. For the reasons set forth below, the Court concludes that the '329 Patent is valid.

A. Claim Construction

The first step in any invalidity analysis is claim construction which is an issue of law. SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp., 225 F.3d 1349, 1355 (Fed. Cir. 2000); Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). A claim term should be construed to mean "what one of ordinary skill in the art at the time of the invention would have understood the term to mean." E.g., Markman, 52 F.3d at 986. Further, when conducting a claim construction analysis, a district court should be cognizant of the fact that claims should be construed, if possible, to uphold their validity. In re Yamamoto, 740 F.2d 1569, 1571 & n.* (Fed. cir. 1984) (citations omitted).

The starting point for a claim construction analysis is the claims themselves. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d at 1582; see also Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999) (stating that "[t]he starting point for any claim construction must be the claims themselves."). Thereafter, the remainder of the intrinsic evidence should be examined beginning with the specification and concluding with the prosecution history. Vitronics, 90 F.3d at 1582 (outlining this order for examination in claim construction).

Generally, there is a strong presumption in favor of the ordinary meaning of claim language as understood by those of ordinary skill in the art. Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). However, it is well-settled that a

patentee may act as his own lexicographer and use the specification to supply implicit or explicit meanings for claim terms. Bell Atl. Network Servs., 262 F.3d at 1268 (Fed. Cir. 2001); Vitronics Corp., 90 F.3d at 1582; Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). "[T]he patentee's lexicography must, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998) (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)).

If the meaning of a claim term is clear from the totality of the intrinsic evidence, than the claim may be construed. If, however, the meaning of a claim term is "genuinely ambiguous" after examining the intrinsic evidence, than a court may consult extrinsic evidence. Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997).

Claim terms in claims 23 and 37 of the '329 Patent are disputed in this case. Accordingly, the Court will focus its discussion on these claims

In full, claim 23 of the '329 Patent provides, "[a] method according to claim 22 wherein said unit dosage of said bisphosphonate comprises about 70 mg of alendronate monosodium trihydrate on an alendronic acid active basis." (PTX 1, '329 Patent at col. 21, lines 24-27) (emphasis added).

In full, claim 37 of the '329 Patent provides, "[a] method according to claim 36 wherein said bisphosphonate unit dosage comprises about 35 mg of alendronate monosodium trihydrate, on an alendronic acid active basis." (PTX 1, '329 Patent at col. 22, lines 24-26) (emphasis added).

Teva contends that the term "about" in claims 23 and 37 should be construed according to its ordinary meaning of "approximately." (D.I. 147 at 3). Merck contends that the patentee in this case acted as his own lexicographer and set out the meaning of "about" in the specification where the specification explains that the term "about" accounts for the variability of weight of the active ingredient that would result from the use of different salts of alendronic acids. (D.I. 141 at 42). Thus, Merck contends that the phrase "about 70 mg" as used in claim 23 and "about 35 mg" as used in claim 37 means 70 and 35 mg respectively of the active ingredient on an alendronic acid active basis. Id. at 43. In other words, Merck contends that, regardless of the final weight of the actual active ingredient in the tablet, it contains the same number of alendronate core molecules as 70/35 mg of alendronic acid.

In rebuttal, Teva contends that Merck's proffered construction makes no sense. Teva points out that according to Merck, the word "about" is used to account for the fact that different alendronate salts have different molecular weights, and that to deliver the same amount of physiologically active compound to the bone they must be delivered at slightly different dosage strengths. (D.I. 147 at 4). Teva contends that Merck's interpretation is nonsensical because the claim itself accounts for this phenomenon by directing that the compound be administered on the basis of a common denominator, i.e., "on an alendronic active basis." Id. In other words, Teva contends that the claims require that the amount "alendronate sodium trihydrate" be sufficient to deliver the same amount of active material as "about 70/35 mg" of alendronic acid. Id. As a result, Teva contends, the term "about" does not perform the function which Merck assigns to it, and must be in the claim for another purpose, that is, to have its ordinary meaning of "approximately."

After reviewing the claim terms and the specification, the Court concludes that the patentee explicitly and with reasonable clarity and precision defined the term "about 70 mg" in claim 23 and "about 35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories. Simply put, no matter what the final weight of the actual active ingredient in the tablet is, it contains the same number of alendronate core molecules as 70/35 mg of alendronic acid.

The relevant portion of the '329 Patent specification provides:

> Because of the mixed nomenclature currently in use by those or [sic] ordinary skill in the art, reference to a specific weight or percentage of bisphosphonate compound in the present invention is on an active weight basis unless otherwise indicated herein. For example the phrase "about 70 mg of bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof and mixtures thereof, on an alendronic acid weight basis" means that the amount of bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

PTX 1, the '329 Patent, col. 10, 65-col. 11, line 8. (emphasis added). The Court concludes that the specification clearly indicates that the terms "about 70 mg" and "about 35 mg" refer to the fact that depending on the derivative of the alendronic acid that could be used in the oral formulation, different weights will be needed in order to get the same effect as 70 or 35 mg of the seminal compound, alendronic acid. As Merck points out, the alendronate sodium in

Fosamax includes an atom of sodium metal for each molecule of alendronate sodium. (D.I. 138 at 24). If a formulator was to select a different salt which includes a metal atom that is heavier than salt, e.g., a potassium or barium atom, the total amount of material in each tablet would have to increase if the amount of alendronic acid were to remain the same. By conforming the weight of the alendronate derivative in the claim of the '329 Patent to the equivalent weight of the alendronic acid, a formulator can consistently know how many basic units (alendronic acid units) are to be used, even though the final total weight may be different. Examples 7 and 8 of the '329 Patent reinforce this conclusion. They provide for oral formulations "containing about 35 mg" and "about 70 mg" of alendronate "on an alendronic acid active basis." The claims at issue use the same phraseology and the ingredient tables in the examples are consistent with the premise that "about" accounts for the fact that alendronate derivatives have accessories that add to the weight of the molecules. Thus, in the examples "about 35 mg" turns out to be 45.68 mg of alendronate monosodium trihydrate and the "about 70 mg" turns out to be 91.35 mg of alendronate monosodium trihydrate. See PTX 1, the '329 Patent col. 19 lines 13-15, col. 19, lines 44-46, col. 19 lines 20-21, col. 19 lines 51-52.

Although the Court finds that Dr. Russell, is competent in the area of bisphosphonates, it does not find his opinion as to the definition of the phrases "about 70/35 mg" in the '329 Patent persuasive. During cross examination on this issue, Dr. Russell testified as follows:

> Q. Now is it true that when you deal with the claims in this case, the claims recite 70 and 35; correct? That is 70 mg a week and 35?
> A. The claims say about 70 and about ....
> Q. And what does "about" mean to you?

A. Well about to me depends how precise a definition we want. But for purposes of how close the 40 and 80 are to about 35 and 70, I've given you my opinion on that, that for practical purposes, those would be the same, they would be indistinguishable in their effects, given everything else we know about the properties of these drugs.
Q. But the claim itself, what the claim really means, is 70, not 80; correct?
A. It says about 70 and about 35.
Q. Did you read the patent, Dr. Russell, the entire body of the patent?
A. Yes, I have.
Q. So in the patent, does it tell you what about 70 means?
A. There is a reference somewhere to about in the patent as I recall, but I'd need to be directed to where it was.
Q. Why don't you go to the first, in the patent, which is Defendant's Exhibit 1 and Plaintiff's Exhibit 1, at column 11, lines about 1 through 9. It says here in the definitional context exactly what about 70 milligrams means; correct?
A. It- well, there's almost an intrinsic contradiction in this, because the definition here is talking about 70, and then referring to whatever salt form is used being referenced to the alendronic acid itself, yes.
Q. But in the patent it gives you a precise reference and says when we say about 70 milligrams of a bone resorption inhibiting bisphosphonate, what we mean is that amount of a bisphosphonate that will deliver an equivalent amount, the equivalent of 70 milligrams of alendronic acid; correct?
A. Yes. I have difficulty with this statement because the reason if it's that precise at 70, why does it use the phrase about?

> Q. But they gave you that exact definition; correct?
> A. It's a curious use of the English language.
> Q. I understand, but it is what it says, and perhaps the person wanted to say if it's a certain salt one, you might use 71, and if it's a certain salt 2, you might use 73. Isn't that what's indicated in this?
> A. Possibly.
> Q. But that's what the definition says; right?
> A. That is the definition as it's described in the patent.

Russell at 337-339. (emphasis added). Although Dr. Russell opined that the explicit definition of the disputed claim terms in the specification was "a curious use of the English Language," he testified that Merck's proffered construction is the definition as it is described in the patent. The Court finds Dr. Russell's interpretation unpersuasive, especially in light of the fact that patentees may give special meanings to claim terms either explicitly or implicitly in patent specifications. Further, with regard to Teva's claim that there is no function to Merck's proffered construction, the Court finds this argument unpersuasive given the clear directive in the specification to construe the term "about 70/35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives and the fact that depending on the derivative of alendronic acid used in the oral formulation, different weights will be needed in order to get the same effect as 70 or 35 mg of alendronic acid. See Bell Atl. Network Servs., 262 F.3d at 1268 (noting that the specification must express a clear intent to redefine a claim term). Accordingly, the Court will accept Merck's proffered construction and construe the disputed claim terms "about 70/35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories.

B. **Anticipation**

Anticipation is determined through a comparison of the claim language with a single prior art reference. See Wesley Jessen Corp. v. Bausch & Lomb, Inc., 209 F. Supp. 2d 348, 391 (D. Del 2002). In pertinent part, 35 U.S.C.§ 102(e) (2) provides:

> A person shall be entitled to a patent unless ...
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351 (a).

35 U.S.C. § 102 (e) (2). Anticipation under 35 U.S.C. § 102 (e) requires that every element of the claim be found either expressly or inherently "in a single prior art reference." In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999). Thus, if the prior art reference does not expressly state an element of the claim, "that reference may still anticipate if that element is 'inherent' in its disclosure." Id. Inherency is established if the evidence makes "clear that the missing descriptive matter is necessarily present in the thing described in the reference and, and that it would be so recognized by persons of ordinary skill." Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Although inherency cannot be established through probabilities, recognition by a person of ordinary skill in the art before the critical date of the patent is not required to show inherent anticipation. Schering Corp. v. Geneva Pharms., Inc., 2003 U.S. App. Lexis 15496 at *9-10 (Fed. Cir. August 1, 2003) (rejecting the contention that inherent anticipation

requires recognition in the prior art before the critical date); In re Robertson, 169 F.3d at 745 (noting that inherent anticipation cannot be demonstrated through probabilities).

1. The Parties' Contentions

Teva contends that a July 1996 Lunar News article expressly anticipates claims 23 and 37 of the '329 Patent. Teva points out that since Merck has stipulated that it does not assert an invention date before July, 22, 1997, the July 1996 Lunar News is prior art under 35 U.S.C. § 102(a). (D.I. 143 at 19). Further, Teva points out that although it has the burden of proving invalidity by clear and convincing evidence, that burden is more easily met in this situation because Merck failed to provide the PTO with the July 1996 Lunar News.

Teva contends that the July 1996 Lunar News discloses every element of claims 23 and 37 of the '329 Patent. Teva points out that claim 23 defines a method of treating osteoporosis which comprises of oral administration of "about 70 mg" alendronate monosodium trihydrate, on an active alendronic acid basis, once-weekly. Similarly, Teva argues the July 1996 Lunar News discloses the same elements where it discusses the use of bisphosphonates, including alendronate, "in dealing with osteoporosis," which means the treatment and prevention of osteoporosis. (D.I. 143 at 21; Russell at 137). Further, Teva contends that the July 1996 Lunar News also specifies that the alendronate therapy it is discussing includes "oral" alendronate therapy, and that the term "alendronate" refers to "Fosamax by Merck." Teva also contends that the active ingredient of Fosamax was well known to be alendronate monosodium trihydrate, and the dosage strength of Fosamax was known to be reported on an alendronic acid basis. (D.I. 143 at 21; DTX

394; Russell at 138-39). Teva also points out that the article specifies that the drug can be administered on a weekly basis at a dose of 80 mg where it states that, " ... oral alendronate potentially could be given in a 40 or 80 mg dose once/week." (D.I. 143 at 21) (quoting DTX 418 at 23). Teva directs the Court to Dr. Russell's testimony where he opines that to a person skilled in the art, 80 mg of alendronate once per week is clinically indistinguishable from 70 mg once a week, and is therefore "about 70 mg." (D.I. 143 at 21; Russell at 138). Teva also contends that Merck itself viewed 80 mg and 70 mg as the same weekly dose. (D.I. 143 at 21; DTX 147 at MK0158265). Thus, Teva contends the July 1996 Lunar News Article discloses every element of claim 23: treatment of osteoporosis by the administration of about 70 mg monosodium trihydrate on an alendronic acid basis once-weekly. (D.I. 143 at 22).

Teva further contends that the July 1996 Lunar News anticipates claim 37 of the '329 Patent. Claim 37 claims a method for preventing osteoporosis in a human being comprising of orally administering about 35 mg of alendronate sodium on an alendronic acid basis as a unit dosage according to a continuous schedule having a dosage interval of once-weekly. (D.I. 143 at 22; DTX 1). Teva points out that the only difference between the two claims is that claim 23 is directed to "treatment" of osteoporosis with a 70 mg weekly dose, and claim 37 is directed to "prevention" with a 35 mg weekly dose. Teva reiterates the contention that the July 1996 Lunar News deals with both the treatment and prevention of osteoporosis and discloses the use of a 40 mg once-weekly oral dose. (D.I. 143 at 22). Teva again directs the Court to Dr. Russell's testimony where he testified that to a person skilled in the art, a 40 mg dose of alendronate once per week is clinically indistinguishable from 35 mg once per week and is therefore "about 35 mg." (D.I. 143 at 22; Russell at 140; DTX 147 at MK0158265). As a result, Teva contends

that the July 1996 Lunar News discloses every element of claim 37: prevention of osteoporosis by oral administration of about 35 mg alendronate monosodium trihydrate on an alendronic acid basis once weekly. (D. I. 143 at 22).

Teva contends that Merck's "fear defense" is irrelevant to anticipation. First, Teva points out that claims 23 and 37 do not require that once-weekly administration of alendronate meet any standard of safety or tolerability. (D. I. 143 at 23). Even if they did, Teva argues, such a requirement would not avoid anticipation because the property of tolerability is inherent in the method disclosed in prior art. Further, Teva argues that the concept of "teaching away" from an invention is inapplicable in an anticipation analysis, and therefore, the Court should not consider it. (D.I. 143 at 24). Based on this, Teva contends that claims 23 and 37 are anticipated by the July 1996 Lunar News, and are therefore, invalid.

In reply, Merck contends that the July 1996 Lunar News fails to anticipate claims 23 and 37 of the '329 Patent. Merck points out that the claims require the use of 70 or 35 mg of alendronate sodium on an alendronic acid active basis and even if one were to read the July 1996 Lunar News suggestion that "[e]ven alendronate potentially could be given in a 40 or 80 mg dose once/week" as referring to the amount on an alendronic acid active basis, 80 mg is not the same as 70 mg and 40 mg is not the same as 35 mg. Merck argues that the unambiguous weight requirement for alendronate in claims 23 and 37 is not met by the Lunar News' suggestion of 80 or 40 mg, and therefore, it fails to anticipate claims 23 and 37. (D.I. 138 at 27). Further, Merck argues that the July 1996 Lunar News is not enabling, and therefore, cannot anticipate. Specifically, Merck contends that in order for a disclosure to be enabling it must allow one of skill in the art to practice the invention, and the July 1996

Lunar News falls short of this standard because it fails to address the expectation by physicians in the field during 1996-1997 that alendronate sodium at doses over 20 mg would not be well-tolerated in the prevention and treatment of osteoporosis. Merck points to Dr. Fennerty's testimony to establish that a knowledgeable gastroenterologist during the applicable period would have been "extraordinarily concerned" about suggesting 40 or 80 mg of alendronate to treat osteoporosis. (D.I. 138 at 28; Fennerty at 270-271).

Further, Merck argues that Dr. Papapoulos, Merck's expert with extensive bisphosphonate and clinical osteoporosis experience, corroborates this sentiment. (D.I. 138 at 28). Merck argues that given the state of the medical knowledge at the time, a physician would not administer those high dosages when managing osteoporosis, and as a result, the July 1996 Lunar News fails to anticipate claims 23 and 37 of the '329 Patent.

2. Whether the July 1996 Lunar News Anticipates the '329 Patent

After a review of the record evidence, the Court concludes that claims 23 and 37 of the '329 Patent are not anticipated under 35 U.S.C. § 102(e) (2). Specifically, the Court concludes that Teva has failed to prove by clear and convincing evidence that the July 1996 Lunar News expressly or inherently discloses the dosage amounts for alendronate in claims 23 and 37. As a threshold matter and contrary to Teva's contentions, it has to prove invalidity by clear and convincing evidence. See American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 1984) (citations omitted) (stating that when a challenger produces prior art not before the PTO "the standard of proof does not change; it must be by clear and convincing evidence

or its equivalent.") With this standard in mind, the Court will consider the parties' contentions with regard to anticipation.

The Lunar corporation was a manufacturer of bone densitometry equipment, which is a diagnostic tool for osteoporosis. (Russell at 129). The Lunar News was a quarterly newsletter distributed by the Lunar Corporation to its customers. (Mazess Dep. at 55-56; Russell at 129). It was authored by Dr. Richard Mazess[1], the former President of the Lunar Corporation. The July 1996 edition[2] contained a section entitled, "Update Bisphosphonate," (PTX 29 at 23). The section discusses bisphosphonates as a treatment for osteoporosis. Id. Specifically, in reference to the use of alendronate for treatment of osteoporosis, it states that "[s]ome United States physicians are reluctant to treat because of: a) side effects; b) difficulty of dosing; and (c) high costs ($700/year). (PTX 19 at 23). To address the difficulty of dosing and high costs the article suggests:

> The difficulties with oral bisphosphonates may favor their episodic (once/week) or cyclical (one week each month) administration. Even oral alendronate potentially could be given in a 40 or 80

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[1] Dr. Mazess does not possess an MD, has no formal training in pharmacology, and obtained his bachelors degree and Ph.D. in anthropology. (Mazess Dep at 30-32).

[2] The Court understands that Teva is not contending that the April 1997 edition of the Lunar News anticipates the '329 Patent. See D.I. 143; Opening Brief at 19-24 (failing to assert that the April 1997 Lunar News anticipates claims 23 and 37 of the '329 Patent). However, even if Teva made this assertion, the Court concludes that the April 1997 Lunar News did not anticipate claims 23 and 37 because it does not suggest any dosage amounts in connection with its discussion of once-weekly dosing of alendronate. (DTX 417). Thus, it does not disclose all of the elements of claims 23 and 37, namely "about 35/70 mg" of alendronate, and therefore, cannot anticipate the claims either expressly or inherently.

> mg dose once/week to avoid dosing problems and reduce costs.

PTX 29 at 23. Teva contends that the July 1996 Lunar News article discloses all of the elements in claim 23 of the '329 Patent. Specifically, Teva argues that the July 1996 Lunar News discloses the following elements: 1) A method of treating osteoporosis in a human; 2) orally administering; 3) about 70 mg; 4) of alendronate monosodium trihydrate; 5) on an alendronic acid active basis; 6) as a unit dosage; and 7) according to a continuous schedule having a dosing interval once-weekly. (D.I. 143 at 23). Merck asserts that the July 1996 Lunar News article does not anticipate claim 23 because it fails to reference 70 mg of alendronate sodium on an alendronic acid active basis as required by claim 23. (D.I. 141 at 44).

After reviewing the July 1996 Lunar News in light of the '329 Patent, and the Court's construction of the claim terms, the Court is not persuaded that Teva has demonstrated by clear and convincing evidence that claims 23 and 37 of the '329 Patent are anticipated by the July 1996 Lunar News. The July 1996 Lunar News fails to reference 70 mg of alendronate sodium on an alendronic acid basis as required by the claim. Instead it references an 80 mg dose of oral alendronate. Thus, it does not expressly disclose "about 70 mg" of alendronate sodium "on an alendronic acid basis." Likewise, the Court is not persuaded that Teva has demonstrated inherency. Although Dr. Russell testified that 80 mg and "about 70 mg" are the same for all practical purposes because they have the same effect on patients, he did not testify that this element was "necessarily present" in the July 1996 Lunar News reference or that its disclosure was sufficient to show that this element was the natural result flowing from the operation as taught. In fact, in the Court's view, Dr. Russell's testimony was insufficient on this issue.

and was, at best, conclusory. For example, although Dr. Russell testified that 80 mg and 70 mg are the same for all practical purposes because they would have the same effect, the Court recognizes that in rendering his opinion Dr. Russell did not take into account the Court's construction of the term "about 70 mg". (Russell at 137-139). Further, the Court notes that Dr. Russell provided no evidence to support his conclusion that 70 and 80 mg were equivalent. In fact, Dr. Papapoulos testified on cross-examination that one would need to test the 80 and 70 mg doses before concluding with any certainty that they are the same and the regulations regarding the filing of an ANDA recognize that any change in the dosage of a drug would require additional data. (Papapoulos at 676-678; 21 U.S.C. § 355 (j)(2); 21 C.F.R. § 314.93). Dr. Russell, provided no such data. Based on this, the Court concludes that Teva has failed to demonstrate that the July 1996 Lunar News inherently or expressly disclosed the element of "about 70 mg" of alendronate sodium "on an alendronic acid active basis" as required by claim 23 of the '329 Patent.

Similarly, the Court concludes that the July 1996 Lunar News fails to disclose "about 35 mg" as required by claim 37 of the '329 Patent. Specifically, the July 1996 Lunar News fails to reference "35 mg" of alendronate sodium "on an alendronic acid active basis" as req red by the claim. Although it references "40 mg", in light of the Court's claim construction of "about 35 mg" to mean the equivalent of 35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories, the Court concludes that the July 1996 Lunar News reference does not expressly disclose "about 35 mg" as required by claim 37. Likewise, the Court concludes that Teva's inherency argument as to claim 37 must also fail. Dr. Russell testified that a 40 mg dose is about the same as a 35 mg for all practical purposes. (Russell art 140-141). However, the

Court finds Dr. Russell's opinion on this issue to be conclusory because he provides no evidence, statistical tests or data to support this assertion. Further, Dr. Russell did not testify that this element was "necessarily present" in the July 1996 Lunar News reference or that its disclosure was sufficient to show that this element was the natural result flowing from the operation as taught. Based on this, the Court finds that the evidence is insufficient to show that each element of claims 23 and 37 of the '329 Patent were present in the prior art reference expressly or inherently. Accordingly, the Court concludes that Teva has failed to establish by clear and convincing evidence that the '329 Patent was anticipated by the July 1996 Lunar News. Because the Court concludes that claims 23 and 37 of the '329 Patent were not anticipated by the July 1996 Lunar News, the Court will not address the parties' contentions concerning enablement of the prior art.

C. **Obviousness**

Teva contends that the '329 Patent is invalid, under 35 U.S.C. § 103, as obvious. In pertinent part, 35 U.S.C. § 103 provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art ..." 35 U.S.C. § 103. The obviousness determination is a question of law which is based on several underlying factual inquiries. See Richardson-Vicks Inc. v. UpJohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997). The underlying factual inquiries require consideration of the four "Graham" factors which are: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) any secondary considerations of nonobviousness such as commercial success, long felt but unsolved need, failure of others, and acquiescence of others in the industry that the patent is valid.

See Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (Fed. Cir. 1996). Additionally, as with anticipation, the burden of demonstrating obviousness is with the challenger and invalidity must be proven by clear and convincing evidence. C.R. Bard, Inc. v. M3 Systems, 157 F.3d 1340, 1351 (Fed. Cir. 1998).

1. The Parties' Contentions

Teva contends that the '329 Patent is invalid as obvious because both the April 1997 and July 1996 editions of Lunar News explicitly disclose the weekly administration of alendronate for osteoporosis and a person skilled in the art would have understood in July 1997 that the weekly dose for treatment and prevention of osteoporosis should be "about 70 mg" and "about 35 mg" respectively, and that these doses are explicitly set out in the July 1996 Lunar News. Teva argues that not only did the Lunar News disclose the concept of once-weekly dosing and provide the appropriate dose, a person of ordinary skill would have predicted the Lunar News teaching to be effective. (D. I. 143 at 26).

Further, Teva contends that there was a motivation to employ once-weekly dosing because of the inconvenience of the dosing regimen which consisted of taking the tablet before eating, remaining upright for a half an hour and taking the tablet with a full glass of water. Id. at 27. Teva points out that the April 1997 and July 1996 editions of Lunar News explicitly stated the motivation to administer alendronate weekly; to improve patient convenience and compliance with the dosing instructions. Id. Thus, Teva argues that the prior art that claimed the invention also disclosed the motivation to make it. Id.

Teva contends that a person of skill in the art would not have been deterred from once-weekly dosing because of the fear of increased gastrointestinal side effects. Id. As to

this point Teva argues that the early reports of esophagitis would not have deterred a person of skill in the art from once-weekly dosing because the early reports showed that these events were rare, occurring in one out of every ten thousand patients taking 10 mg of alendronate daily, and that these effects were for the most part reversible with proper treatment. Id. at 28; Markowitz at 436-37; 451. Teva also points out that in March 1996, five months after the launch of 10 mg daily alendronate tablet, ten million patients had been prescribed the tablet and fifty cases of severe esophagitis had been reported to Merck, and Merck took no action until it learned that a letter written by a well-known bone-specialist discussing two such cases was circulating within the Mayo Clinic Health System. D.I. 143 at 29; Hirsch Dep. at 54-56). When it finally took action, Teva argues, Merck's investigation concluded that the pill esophagitis cases were caused primarily by the failure of patients to adhere to the dosing instructions. (D.I. 143 at 29; Markowitz at 442; Hirsch Dep. at 66; 82-84).

Teva also points out that in March 1996, Merck disseminated a "Dear Doctor" letter, informing physicians about the infrequent cases of esophagitis, stating that in a "large majority" of cases patients appeared to have not complied with the dosing instructions, and advocating "strict compliance" with those instructions. (D.I. 143 at 30; DTX 34). Merck later reported on the severe esophagitis cases in the October 1996 De Groen et al.[3] article in the New England Journal of Medicine. (PTX 91). The De Groen paper reported that 51 patients experienced adverse effects classified as "serious" or "severe" out of the 470,000 patients worldwide who had received prescriptions for alendronate to treat osteoporosis up to that time. (D. I. 143 at 30). Teva

[3] De Groen et al., The New England Journal of Medicine, 1996 (PTX 91).

directs the Court to its gastroenterology expert, Dr. David Markowitz, who testified that the extremely low incidence of these effects, and the description of the cases, led gastroenterologists to conclude at the time that the likely cause of the problem was "pill esophagitis."(D.I. 143 at 30; Markowitz 435, 438). Teva argues that the evidence presented at trial leads to the conclusion that once-weekly administration would have been expected to decrease the incidence of severe esophagitis cases because it would: 1) improve patient compliance with the dosing instructions (Russell at 195-96; Markowitz at 485-86; Fennerty at 311); and 2) decrease the frequency of administration, thereby decreasing the chances of the tablet "sticking" in the esophagus (Russell at 196-197; Markowitz at 443).

Teva also asserts that the evidence presented at trial does not support a dose-response relationship between alendronate and gastrointestinal effects that would have deterred a person of ordinary skill in the art from once-weekly dosing. (D.I. 143 at 32). For example, Teva argues that the results of the Chestnut[4] study related to daily and not weekly dosing and demonstrated that 90% of postmenopausal women with osteoporosis tolerated the 40 mg daily dose. Id. at 34. Also, Teva contends that Dr. Fennerty's testimony regarding a dose-related relationship was discredited by Merck's pre-litigation behavior and directs the Court to the testimony of Dr. Markowitz who testified that his contemporaneous investigations indicated that severe events were extremely rare with alendronate and that overall the drug was well tolerated. Id. at 35.

In addition, Teva contends that before this litigation, Merck admitted that prior art data available in July 1997 from Paget's patients showed that once weekly dosing would

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[4] Chestnut et al., The American Journal of Medicine, 1995, (PTX 69).

be well-tolerated. For example, Teva directs the Court to a May 1997 "Tactical PAC" review seeking management approval to go forward with the once-weekly dosing program where it stated that "the 40 and 80 mg doses were well-tolerated even when given on a daily basis." (D.I. 143 at 39, DTX 147 at MK0158265). Further, Teva points out that Merck, in a formal submission to the FDA maintained that data from Paget's disease provided an expectation that once-weekly doses would be well tolerated. (D.I. 143 at 39; DTX 192 at 17).

Teva also argues that a person of skill in the art would not have been deterred from once-weekly dosing because of the alleged dose-related effects of prior art bisphosphonates, because the magnitude of data available on alendronate in treating osteoporosis and Paget's disease made reference to other bisphosphonates unnecessary. (D.I. 143 at 41). Teva also points out that Merck's Physician Survey conducted in 1997 indicated that physicians perceived that larger less-frequent doses would result in "less-GI upset." (D.I. 143 at 43; DTX 244 at MK0174861).

Teva also contends that the '329 invention did not provide unexpected results because the prior art disclosed its principal advantage; convenience and compliance. (D.I. 143 at 44). Additionally, Teva contends that Merck did not carry its burden of demonstrating commercial success because it was required to show that the once-weekly product contributed to the incremental success beyond the daily product and that Merck's expert, Dr. Vellturo failed to demonstrate any connection between the patented invention and Merck's sales of once-weekly Fosamax. Specifically, Teva contends that Dr. Vellturo did not opine that the two were connected but merely asserted that "commercial success could be at least in part, significant part, attributable to the Daifotis patients." D.I. 143 at 48; Vellturo at 715. Further,

Teva suggests that Dr. Vellturo's analysis is flawed because of his emphasis on sales and prescriptions as the only indicia of success without considering any other market factors such as the increased awareness about osteoporosis and the effect of the increasing number of Americans over the age of sixty, like its own expert, economist, Dr. Richard Rozek took into account. (D.I. 143 at 48). Additionally, with regard to commercial success, Teva contends that Merck ignored its own successful marketing efforts such as its heavy promotional expenditures during the applicable period when examining the commercial success of the once-weekly dose of alendronate. (D.I. 143 at 51). Finally, Teva argues that Dr. Vellturo's diffusion model is flawed because a diffusion model in not particularly useful as a forecasting devise, and therefore, its use in this context is inappropriate and alternatively argues that Dr. Vellturo's use of the model is incorrect. (D.I. 143 at 54).

In response, Merck contends that the once-weekly high dose regimen of the '329 Patent was not obvious to a skilled practitioner in 1997 because without hindsight, the overwhelming knowledge in the field was that high oral unit doses would not be safe and tolerable for osteoporotic women. Merck points out that Dr. Russell, Teva's expert, acknowledged that a person of ordinary skill "would be familiar with publications in the field and the technical background in this field of bisphosphonates and osteoporosis." (Russell at 144). Thus, according to Dr. Russell's interpretation of one of ordinary skill, Merck argues, a skilled practitioner would know that: 1) etidronate and clodronate caused gastrointestinal side effects at high doses; 2) pamidronate caused dose-related gastrointestinal side effects that even led to the discontinuation of its development as an oral medication; 3) alendronate caused dose-related gastrointestinal side-effects; and 4) alendronate sodium, even though proven to be safe and tolerable at 10

and 5 mg doses, could still potentially cause severe upper gastrointestinal injuries. (D.I. 145 at 10-11) (citations omitted). Merck contends that the overwhelming knowledge, laid out by contemporaneous publications in respected peer-reviewed medical journals establishes that the pre-invention expectation by those skilled in the art was that one could not use alendronate sodium at unit doses higher than 20 mg for the management of osteoporosis. Id. at 11.

Further, Merck asserts that Teva's "spin" on the Chestnut study is flawed. Specifically, Merck points out that in the Chestnut study only one out of sixty two women (1.6%) withdrew from the 10 and 5 mg doses, but seven out of sixty three women (11.1 %) withdrew from the 40 mg alendronate treatment. Id.; PTX 69 at 150; Markowitz at 479-482; Fennerty at 266. Moreover, contrary to Teva's assertion, Merck points out that it informed the FDA that the Chestnut Study had led it to "limit the maximum dose to 20 mg in subsequent osteoporosis treatment studies." (D.I. 145 at 15; PTX 202 at MK250180; PFF 66). Additionally, Merck asserts that as Dr. Papapoulos testified, a skilled practitioner at the time knew that in actual clinical practice 10 to 12 percent of patients discontinued 10 mg Fosamax treatment because of gastrointestinal side effects. (D.I. 145 at 12; Papapoulos at 651-652). Thus, Merck argues that any reasonable clinician, viewing this data could compare these ratios and would expect the discontinuation rate for osteoporotic women in actual practice, outside the confines of a controlled clinical environment, to have been unacceptably high at a 40 mg dose. Merck asserts that Teva failed to consider that clinical studies are different than daily practice and that discontinuations are far less common in the context of a clinical study. (D.I. 145 at 12; PFF 60; Fennerty at 262-64).

In reference to Teva's reliance on internal and FDA submitted documents, Merck contends that these publications as presented by Teva were taken out of context, and therefore, do not bolster Teva's argument with regard to obviousness. Merck argues that Teva improperly relied on these documents because these documents reflect the inventors' rationales to overcome the skepticism about high unit doses and the inventors' insights about their own invention. In regard to extrapolating results from the Paget's disease experience to doses for osteoporosis, Merck points out that Professor Fleish's book, which Dr. Russell later edited, reflected the thinking in the art that the tolerability for alendronate sodium appeared to be higher for the pagetic disease population than the osteoporosis population. (D.I. 145 at 15).

Merck also contends that it has never disputed that it was known that once-weekly dosing would be efficacious in providing the alendronate sodium needed to inhibit bone resorption, but notes that it was the safety concern about high oral doses (higher than 20 mg) that obscured the advantageous once-weekly invention for the management of osteoporosis. (D.I. 145 at 15). Further, Merck points out that it did not rely on the case reports such as De Groen as evidence of a dose-response, rather, Merck claims, the case reports simply raised the awareness of physicians that alendronate sodium was a potentially dangerous agent and that Teva's expert, Dr. Markowitz admitted that the case reports were clinically significant. (D.I. 145 at 18; Markowitz at 468). Merck also rebuts the contention that it took no action in response to the case reports and points out that it promptly obtained data about each case, constructed a data base and organized a meeting with Dr. De Groen and other consultants by March 1996. Then, on March 15, 1996 Merck sent out a "Dear Doctor" letter informing physicians about the potential upper gastrointestinal injuries and emphasizing

the importance of following directions in order to minimize them. Merck also undertook internal studies to understand the problem, including dog studies. (D.I. 145 at 19; PTX 67; PFF 88).

In reference to Dr. Fennerty's testimony, Merck contends that Teva mischaracterized his testimony regarding the Blank[5] article. Merck asserts that the Blank study provided a glimpse as to what happens when the use of aminobisphosphonates is combined with Non-Steroidal Anti-Flammatory Drugs ("NSAIDs") such as aspirin and ibubrofen. This study was published during February of 1997 in the peer reviewed Digestive Diseases and Sciences, and it showed clear dose-related upper gastrointestinal injuries from alendronate sodium when it was combined with the NSAID indomethacin in a rat model. (D.I. 145 at 20; PTX 104 at 284 fig. 3). Merck contends that Dr. Fennerty observed that when placed in the mosaic of prior art showing the dose dependent injuries from bisphosphonates, the Blank study was important to gastroenterologists, and he never retreated from this position. (Fennerty at 270, 292-94). Additionally, Merck points out that Teva itself stated to the PTO in 2000, in an attempt to gain the issuance of claims for a delayed gastric release alendronate formulation, that bisphosphonates as a class exhibit side effects that "consist of irritation of the upper gastrointestinal mucosa ... with the potential for this irritation leading to more serious conditions." (PTX 301, U.S. Patent No. 6,476,006 ("the '006 Patent") at col. 3, lines 25-25). Merck contends that Teva also told the PTO that the "larger" once weekly doses have "the potential of exacerbating the upper GI side effects of the drug." D.I. 145 at 21 (quoting the '006 Patent at col. 3, lines 12-14).

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[5] Blank et al., Digestive Diseases and Sciences, 1997 (PTX 106).

Merck argues that Teva's reliance on the 1997 Physicians Survey is misplaced because it did not address the use of higher doses. Specifically, Merck points out that at issue is the invention of administering seven-fold the daily dose of alendronate sodium once a week, and in the survey, a twice-weekly dosing schedule was inquired about along with other choices that included placing alendronate sodium in diet colas and cranberry juice. (D.I. 145 at 22; DTX 244 at 174866). Merck points out that the invention of the '329 Patent does not lie solely in the less frequent dosing, but in the fact that an entire weekly complement of daily doses could be administered as a single unit dose and that the marketing survey inquired about twice weekly dosing without any mention of increasing the dose. Therefore, Merck argues that it does not bear any relevance to the invention of once-weekly dosing at sevenfold the daily dose. (D.I. 145 at 22).

In regard to secondary considerations, Merck contends that contrary to Teva's assertion that commercial success is irrelevant in the obviousness inquiry because Merck was the only entity allowed to market alendronate sodium tablets, its direct competitors, including Procter & Gamble, had an incentive to develop an improved dosage form. (D.I. 145 at 23). Further, in reference to commercial success, Merck contends that the increased sales for the Fosamax franchise upon the launch of the once-weekly dosing regimen is dramatic regardless of which way it is viewed. (D.I. 145 at 25). Specifically, Merck points out that the Fosamax franchise sales followed a constant increase trend from 1996 until the introduction of once-weekly Fosamax in 2000, where if the trend established before the once-weekly dose was introduced had continued, an increase of 18.9% over the prior year would have resulted. However, after the once-weekly dosing was introduced, a dramatic increase of 42.5% was realized. (D.I. 145 at 26; PTX 166;

Vellturo at 718-720). Additionally, Merck contends that Teva's attempt to discredit Dr. Vellturo's diffusion model was unsuccessful. Merck argues that, in any event, Dr. Vellturo testified that his opinion regarding the commercial success of the '329 Patent was not based on model, but on a fundamental shift in the constant trends he observed regarding the Fosamax franchise's sales increases, market share, prescription volume and on an evaluation of the market share and prescription volume data for the osteoporosis market as a whole, and that the diffusion model only confirmed the opinion he formed based on the aforementioned factors. (D.I. 145 at 26; Vellturo at 718-728, 735; 755-757). Finally, Merck notes that Dr. Rozek, Teva's expert on obviousness, provided no ultimate conclusion about the commercial success of the once-weekly dosing of Fosamax or any of the factors he believed Dr. Vellturo should have considered. (D. I. 145 at 26).

2. Whether the '329 Patent Was Obvious in View of the Prior Art

After reviewing the relevant prior art in light of the evidence and the factors related to the obviousness inquiry, the Court concludes that Teva has failed to establish by clear and convincing evidence that the '329 Patent was obvious in light of the prior art references. The Court in its obviousness analysis must be cognizant of "hindsight syndrome." In re Warner Kotzab, 217 F.3d 1365, 1369-1370 (Fed. Cir. 2000). The Federal Circuit has instructed that, "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." In re Gartside, 203 F.3d 1305; 1329 (Fed. Cir. 2000). Therefore, in order to establish obviousness from a combination of elements disclosed in prior art, "there must be some motivation, suggestion or

teaching of the desirability of making the specific combination that was made by the applicant." Kotzab, 217 F.3d at 1370. With this standard in mind, the Court will discuss the relevant factors of the obviousness inquiry as they relate to the '329 Patent.

i. Level of One Skilled in the Art

For the purposes of the obviousness inquiry, the Court finds that at the time of the filing of the '329 Patent, a person of ordinary skill in the art was an individual who would have an M.D. and/or Ph.D. and was working in the field of and doing research on osteoporosis. Such a person would be familiar with the publications and technical literature and background in the field of bisphosphonates and osteoporosis. (D.I. 142 at 17-18; D.I. 141 at 41). The Court bases this finding on a combination of Merck and Teva's proffered interpretation of one skilled in the art and finds that there are no significant differences between the two proffered definitions.

ii. Scope and Content of Prior Art

At the outset, the Court notes that Merck has never disputed that it was known that once-weekly dosing would be efficacious in providing the alendronate sodium needed to inhibit bone resorption. (D.I. 145 at 15). However, Merck contends that it is the safety concern about high oral doses, specifically unit doses higher than 20 mg, that obscured the advantageous once-weekly invention for the management of osteoporosis. Id. Thus, the issue is when viewing the mosaic of the prior art, whether those of ordinary skill in the art would have had the motivation to formulate a once-weekly seven-fold daily dose of alendronate sodium, despite safety concerns.

The Court concludes that the history of bisphosphonates as a class is minimally relevant to the instant discussion because although alendronate is a bisphosphonate and general knowledge of bisphosphonates is certainly within the knowledge of one of ordinary skill in the art during the relevant time period, it was also well known that each bisphosphonate had its own unique characteristics. (See DTX 547 at 543) (Dr. Papapoulos, Merck's expert, noting that because of differences in mechanisms of action and pharmacological and toxicological profiles, it is "important that specific properties of every individual bisphosphonate be determined and that results obtained with one bisphosphonate not be extrapolated readily to the whole class."). As a result, although the earlier bisphosphonates etidronate, clodronate and pamidronate had dose related gastrointestinal side effects, the Court concludes that this fact holds little weight in its obviousness analysis given the unique characteristics of each bisphosphonate, particularly with side effects. (Papapoulos at 653-654; Russell at 384-385; PTX 110 at 127, 129, 130; PTX 111 at 148, 149, 152; PTX 112 at 154, 15, 1585; PTX 113 at 170, 171, 175; PTX at 289, E91, C278, C279).

Therefore, the Court will focus its discussion on the prior art dealing with alendronate. The 1995, 1997, and 2000 editions of "Bisphosphonates in Bone Disease" written by Professor Herbert Fleish, who is described as the "father of bisphosphonates", reported that oral alendronate sodium can cause gastrointestinal disturbances at doses of 40 mg. (PTX 111 at 148; PTX 112 at 153; PTX 113 at 169; see also PTX 300 at 26). Further, in the 1997 and 2000 editions, Dr. Fleish reported that a 40 mg dose may cause gastrointestinal disturbances in patients with osteoporosis, but that the same dose was well tolerated in patients with Paget's disease. (PTX 112 at 153; PTX 113 at 169).

Additionally, the Court finds that case reports are probative in its obviousness inquiry because, as Dr. Fennerty testified, they often contain information that would alter the way a physician would treat patients. (Fennerty at 247-248). Case reports are publications usually involving one or a few patients that have an outcome of clinical relevance or importance. (Fennerty at 246-247). In October 1995, Maconi[6] published a case report in the American Journal of Gastroenterology, which reported that an osteoporosis patient after taking 5 mg of alendronate, had an endoscopy which revealed severe damage to the esophagus. (Fennerty at 249-250). Dr. Fennerty testified that this case report was significant because the particular journal it was published in was "clinically relevant" and because this "severity of injury had never been reported in a patient taking a bisphosphonate prior to this, especially a bisphosphonate that was being used now very commonly in clinical practice as it had just been released at about the time the case report was published." (Fennerty at 250). In October 1996, De Groen published an article in The New England Journal of Medicine which set out three case reports describing the side effects of alendronate sodium. (PTX 91). The first case report reported that a 73-year-old woman developed chest pain and dysphagia after her first dose of 10 mg of alendronate sodium. (PTX 91 at 1016-1017). After two more doses she was transferred to the Mayo Clinic where an endoscopy revealed severe ulcerative esophagitis. (PTX 91 at 1017; Fennerty at 254-56). The other two case reports revealed that two additional women developed severe esophageal injury as a result of taking 10 mg oral dose of alendronate sodium. (PTX 91 at 1017; Fennerty 254-256). The article also revealed that Merck revised dosing instructions in the Fosamax product circular based on the results noted in the

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[6] Macon, The American Journal of Gastroenterology, (1995) (PTX 90).

paper so as to further minimize potential for prolonged contact of the drug with the esophagus and thus, to reduce the risk of injury. (PTX 91 at 1020). Additional case reports published by Abdelmalek (PTX 96), Sorrentino (PTX 98), Naylor (PTX 101), Rimmer (PTX 102), Pizzanni (PTX 109) and Girelli (PTX 106) also suggested evidence that alendronate sodium may be associated with severe side effects not recognized in clinical trials. (Fennerty at 259).

The Court also finds that several studies dealing with alendronate are significant. In 1993, Harris[7] published an early Phase II study, which is a dose-ranging study used to determine the dose and the preliminary data on both the safety and efficacy of a drug, sponsored by Merck in the Journal of Clinical Endocrinology and Metabolism investigating the effects of oral alendronate sodium treatment. (PTX 116; Russell at 159, 364-65). The women in this study were between the ages of 40 and 60 and did not have osteoporosis. The women were treated with alendronate sodium doses from 5 to 40 mg for six weeks and the dosages were well-tolerated. (PTX 116 at 1399).

Merck then sponsored a study investigating the effects of a range of different oral doses of alendronate for the treatment of osteoporosis. (PTX 69). The results of this study were published by Chestnut in 1995 in the American Journal of Medicine. The Chestnut study lasted for two years and involved 188 women with osteoporosis. (PTX 69; Yates at 502-504). Of these women, 31 were exposed to placebo, 32 to 5 mg, 30 to 10 mg, 32 to 20 mg and 63 to 40 mg of alendronate sodium. (PTX 69 at Table 1). As of 1996, the Chestnut study was the only study that administered alendronate sodium to osteoporosis patients. (PTX 69;

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[7] Harris, Journal of Clinical Endocrinology and Metabolism, (1993) (PTX 116).

Markowitz at 478-479). Chestnut reported that nine women discontinued alendronate sodium therapy due to gastrointestinal side effects that included nausea, dyspepsia, mild esophagitis/gastritis and abdominal pain. (PTX 69 at 150; Markowitz at 479-482; Fennerty at 265-66). Nine women withdrew from treatment because of these side effects: seven women withdrew from the 40 mg dose, one woman withdrew from the 20 mg dose and one women withdrew from the group taking between 5 and 10 mg doses. (PTX 69 at 150; Markowitz at 479-482; Fennerty at 266; Yates at 539-540). Chestnut also reported that the gastrointestinal side effects "occurred primarily in the first year during treatment with 40 mg alendronate." (PTX 69 at 150, col. 1). Dr. Fennerty testified that the fact that 11.1% (7 out of 63) withdrew from the 40 mg alendronate dose was noteworthy within the context of a clinical trial.[8]

Teva contends that the April and July 1996 editions of the Lunar News render claims 29 and 37 of the '329 Patent obvious. The July 1996 Lunar News issue contained a section entitled, "Update Bisphosphonate." (PTX 29 at 23). The section discusses bisphosphonates as a treatment for osteoporosis. Id. In reference to the use of alendronate for treatment of osteoporosis, it states that "[s]ome United States physicians are reluctant to treat because of: a) side effects; b) difficulty of dosing; and (c) high costs ($700/year)." (PTX 19

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[8] The Court concludes that studies dealing with Paget's disease are not relevant to its analysis because it was well-known to those of ordinary skill in the art that patients with Paget's disease tolerate higher doses of alendronate than patients with osteoporosis. (Papapoulos at 710-711; PTX 112 at 153; PTX 113 at 169; see also PTX 300 at 26). Thus, the Court finds that tolerability of alendronate sodium from studies involving Paget's patients should not be extrapolated to a discussion of osteoporosis about the tolerability of alendronate. For this reason, the Court will not address studies dealing with Paget's disease and the tolerability of higher doses of alendronate sodium.

at 23). To address the difficulty of dosing and high costs the article suggested:

> The difficulties with oral bisphosphonates may favor their episodic (once/week) or cyclical (one week each month) administration. Even oral alendronate potentially could be given in a 40 or 80 mg dose once/week to avoid dosing problems and reduce costs.

PTX 29 at 23. In a section entitled "Update: Bisphosphonates," the April 1996 edition of the Lunar News discusses difficulties of the dosing regimen associated with alendronate and states:

> one of the difficulties with alendronate is its low oral bioavailability. When taken with water in a fasting state, only about 0.8% of the oral dose is bioavailable. Even coffee or juice reduces this by 60%, and a meal reduces it by > 85%. Alendronate must be taken, after an overnight fast, 30-60 minutes before breakfast. Subjects should remain seated or standing; a very small group of patients have reported some upper gastrointestinal distress if this is not done. This regime may be difficult for the elderly maintain chronically. An intermittent treatment program (for example, once per week, or one week every three months), with higher oral dosing, needs to be tested.

DTX 417 at 31. (citations omitted).

iii. Differences Between the Prior Art and the Claims at Issue

The Court concludes that the prior art cited above demonstrates that the suggestion to give 40 or 80 mg of

alendronate sodium to treat or prevent osteoporosis was not clinically useful or obvious in July 1997 because of the known dose-related gastrointestinal side effects. Further, the Court is not persuaded that the two Lunar News articles, not published in peer-reviewed journals or authored by one skilled in the art, either alone or in combination, overcame the serious side effect concerns associated with higher dosage units of alendronate sodium. For example, Dr. Fennerty, whom the Court finds very credible, testified that in light of the prior art, any physician would have been "extraordinarily concerned" to suggest a 40 or 80 mg dose because alendronate sodium was a new compound that had been associated with dose-related injury and severe injuries in case reports. (Fennerty at 270-271; see also PTX 69, 91, PTX 300 at 14). In this regard Dr. Fennerty testified:

> Q: Now in July of '97 or any period preceding that, what would your opinion be about a suggestion that you give 40 or 80 milligrams of alendronate to an osteoporotic woman?
> A. Given what I just described, a new compound, a Dear [D]octor letter, publications in the New England Journal of severe caustic injury, smattering case reports around that, the Chestnut [sic] paper before talking about as you go up on a dose, that you may be seeing more adverse effects, the smattering of papers, and now animal data showing that types of patients that use NSAIDS use some higher dose of these compounds, shows evidence of gastric injury in the model, I would have been extraordinarily concerned about anybody suggesting that this was a useful clinical approach at that point and time.

(Fennerty at 270-21). Additionally, Dr. Papapoulous testified about the concerns of side effects associated with the

suggestion in the July 1996 Lunar News where he stated, "[Lunar News] is using 40 and 80 not on any scientific rationale, but because it is available. Secondly, he doesn't tell us how he's going to address the issue of side effects, which is one of the main points in this particular article." Papapoulos at 665-666. Thus, in light of the case reports, and the Chestnut study, in conjunction with observations written about alendronate by Dr. Fleish, the Court concludes that the Lunar News references did not render the seven-fold daily dose of alendronate for the treatment and prevention of osteoporosis obvious given the clearly documented and known dose related gastrointestinal side effects associated with high doses (over 20 mg) of oral alendronate.

First, the April 1997 Lunar News did not deal with the specific dosages of 70 or 35 mg in relation to its discussion of once-weekly dosing of alendronate. Second, the July 1996 Lunar News listed 40 and 80 as compared to 70 and 35 mg dosages as suggested by the '329 Patent and did not deal with the problem of known gastrointestinal side effects. Additionally, in reaching its conclusion, the Court gives more weight to the prior art references written and reviewed by those skilled in the art such as the Chestnut study and the De Groen case report as opposed to the Lunar News, a quarterly newsletter written by someone without a Ph.D. or MD. in the applicable field.

iv. Secondary Indicia of Non-Obviousness

As for the secondary considerations of non-obviousness, the Court finds that Merck has presented sufficient evidence to show that the 35 mg and 70 mg once-weekly dosing of Fosamax was commercially successful. On this issue, the Court finds Dr. Vellturo's testimony persuasive.

Dr. Vellturo testified regarding the evidence of increased sales after the launch of once-weekly Fosamax.

Originally, Merck's Fosamax osteoporosis product line consisted of once-daily 10 and 5 mg Fosamax tablets. (D.I. 138 at 32). Dr. Vellturo testified that daily Fosamax was a successful product that enjoyed an average increase in sales of 152 million dollars per year for each of the four years preceding the introduction of the once-weekly Fosamax. (Vellturo at 718-720; PTX 166; PTX 300 at 37). In 2001, the first full year following the launch of the once-weekly dosing regimen, the sales increase was 343 million dollars, more than double the expected increase, without any corresponding relative increase in expenditures. (Vellturo at 719-720; PTX 166; PTX 300 at 37).

The Court finds that further evidence of the success of the once-weekly dosing regimen is present in the prescription data for the Fosamax tablets. A sharp increase in physician adoption of Fosamax upon the introduction of the once-weekly dosing regimen is manifested in the number of total prescriptions reported each month for Fosamax. (Vellturo at 723; PTX 164; PTX 300 at 32, 33, 36). The marked increase in prescription volume of once weekly dosages of Fosamax tablets is more compelling in light of its effects on the osteoporosis market in general. FAME is an acronym for the four prescription drug products whose primary indication is for the treatment of osteoporosis, (i.e., Fosamax, Actonel, Miacalcin, and Evista). (Vellturo at 722, 753-754). IMS is a data collection firm specializing in data reflecting the prescribing patterns of physicians and in prescription volume data. (Vellturo at 716-717). Within six months of its launch, once-weekly Fosamax tablets became the most prescribed drug in the FAME market. (PTX 164; PTX 165; PTX 300 at 33). Based on the IMS data points present in the plot of monthly total prescriptions, it can be

calculated that the Fosamax franchise share of the FAME market grew from 45 % to 55 % in the first six months after the introduction of the once-weekly dosing regimen. (PTX 164; PTX 300 at 33).

Teva's expert Dr. Rozek testified that the increase in Fosamax sales could be due to other factors such as the increasing number of Americans over the age of sixty, the increasing awareness of osteoporosis, an increase in the number of people seeking treatment for osteoporosis and Merck's marketing efforts. However, the Court finds Dr. Rozek's explanation unpersuasive because he offered no affirmative opinion as to what affect these factors would have on the analysis of the FAME market as a whole or with Fosamax individually. (Rozek at 871-72; 869; 878). In fact, Dr. Rozek testified the he was "not instructed to do anything affirmative with regard to the mea[illegible]ng of any relationship that might exist between the ['32[illegible] Patent] and sales, or success of Fosamax." (Rozek at 869). In the Court's view, Dr. Rozek's suggestion that there are factors that Dr. Vellturo should have considered, is not sufficient to rebut the affirmative evidence of the commercial success of the once-weekly dosing regimen. (Rozek at 878-79). Also, the Court concludes that Merck has shown a sufficient nexus between the claimed secondary considerations and the patented method given the testimony of Dr. Vellturo and the timing of the launch of the once-weekly dosing regimen for Fosamax. Accordingly, the Court has given the above discussed secondary considerations the importance they deserve in reaching its conclusion of nonobviousness. See Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopedics, Inc. 976 F.2d 1559, 1573 (Fed. Cir. 1992) (noting the importance of secondary considerations in the obviousness analysis).

v. Summary

In sum, the Court concludes that Teva has not proven by clear and convincing evidence that it was obvious to combine the Lunar News suggestions in light of the knowledge of one of ordinary skill in the art of the gastrointestinal side effects accompanying large doses of oral alendronate. In addition, the Court finds that the significant secondary considerations offered by Merck undermine any claim of obviousness, and accordingly, the Court concludes that Teva has not proven by clear and convincing evidence that the '329 Patent was obvious in light of prior art.

V. Unenforceability Due To Inequitable Conduct

A. The Inequitable Conduct Standard

As a general matter, patent applicants and their patent attorneys have a duty of candor, good faith and honesty in their dealings with the PTO. 37 C.F.R. § 1.56(a). The duty of candor, good faith and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F. 3d 28, 30 (Fed. Cir. 1999). Breach of the duty of candor, good faith and honesty may constitute inequitable conduct. Id. If it is established that a patent applicant engaged in inequitable conduct before the PTO, the entire patent application so procured is rendered unenforceable. Kingsdown Medical Consultants v. Hollister Incorporated, 863 F.2d 867, 877 (Fed. Cir. 1988).

A patent applicant engages in inequitable conduct before the PTO when he withholds or misrepresents information material to the patentability of his invention, with an intent to deceive.

See Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1064 (Fed. Cir. 1998); (citing Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)). Inequitable conduct encompasses affirmative misrepresentations of material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. Baxter Int'l, Inc. v. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998) (citing Nobelpharma, 141 F.3d at 1068-71). In order to establish unenforceability based on inequitable conduct, Teva must prove, by clear and convincing evidence, that material information was intentionally withheld for the purpose of misleading or deceiving the patent examiner. See Allied Colloids, Inc. v. American Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995) (citation omitted).

A determination of inequitable conduct entails a two step analysis. First, the court must determine whether the withheld information meets a threshold level of materiality. A reference is considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. See id. This determination is not the end of the inquiry with respect to intent. The Federal Circuit has stated that, "materiality does not presume intent, which is a separate and essential component of inequitable conduct." See Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 552 (Fed. Cir. 1990) (internal citation omitted).

After determining if the applicant withheld information that is material, the court must then determine whether the evidence demonstrates a threshold level of intent to mislead the PTO. See Baxter, 149 F.3d at 1327. "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." Hebert v. Lisle Corp., 99

F.3d 1109, 1116 (Fed. Cir. 1996). Therefore, in order to satisfy the intent to deceive element of inequitable conduct, the conduct when viewed in light of all of the evidence, including evidence of good faith, must demonstrate sufficient culpability to require a finding of intent to deceive. See Paragon Podiatry Lab., Inc. v. KLM Lab, Inc., 984 F.2d 1182, 1189 (Fed. Cir. 1993).

The initial determinations of materiality and intent to deceive are questions of fact. See Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001) (citation omitted). Once these facts are established, the court should then weigh the findings and their premises and determine, in its discretion, whether to hold the patent unenforceable. See ATD Corp. v. Lydall, Inc., 159 F.3d 534, 547 (Fed. Cir. 1998).

B. **Whether Dr. Yates Engaged In Inequitable Conduct Before the PTO Rendering The '329 Patent Unenforceable**

Teva contends that Dr. Yates engaged in inequitable conduct before the PTO rendering the '329 Patent unenforceable. Specifically, Teva contends that Dr. Yates intentionally withheld the July 1996 edition of the Lunar News from the Patent Examiner.

In response, Merck contends that the July 1996 Lunar News was not considered material because it was cumulative to the cited prior art. Merck further contends that Dr. Yates did not make any material misrepresentations to the PTO, and that Teva cannot establish an intent to deceive the PTO by clear and convincing evidence.

1. The Allegedly Withheld Prior Art

In the Court's view, the July 1996 Lunar News has some degree of materiality because it has relevance to the claimed invention, specifically, the recommended once-weekly dosage level of alendronate for osteoporosis patients. Additionally, the Court finds that it is not cumulative to the cited prior art, specifically the April 1997 Lunar News because, although the April edition mentions a 40 mg dose of alendronate it does not suggest a 40 or 80 mg dose in the context of once-weekly dosing as the July 1996 edition of the Lunar News does. However, as previously discussed, the Court finds that the July 1996 Lunar News does not reflect the claimed invention directly and does not render the claimed invention invalid as either obvious or anticipated. See, e.g., Life Technologies, Inc. v. Clontech Labs. Inc., 224 F.3d 1320, 1325 (Fed. Cir. 2000) (citing 35 U.S.C. § 103(a) and stating that "the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute").

2. Intent to Deceive

The Court concludes that Teva has failed to meet its burden of demonstrating a prima facie showing of intent to deceive the PTO. As to this issue, Teva contends that Dr. Yates' testimony indicating that he did not read the July 1996 Lunar News was not credible in light of the fact that in September 1996, Dr. Yates received a memorandum discussing Lunar News' comments about alendronate, with the relevant portions of the July issue attached. Further, Teva argues that Dr. Yates' testimony that he did not focus on the July 1996 issue again on May 21, 1997 at a meeting with Lunar Corp., where the July 1997 issue was attached as an agenda item, is not credible.

The Court finds that this evidence of intent to deceive falls short of the applicable standard. Dr. Yates testified unequivocally that he had never seen the statements regarding once-weekly dosing of alendronate in the July 1996 Lunar News prior to this litigation. (Yates at 533-34; 572-573; 575). Additionally, in reference to the September 1996 memo that was circulated with the July 1996 Lunar News as an attachment, the Court recognizes that there were twelve pages attached to the original memo and the relevant article in the July 1996 Lunar News was the last page. Based on this, the Court finds Dr. Yates' testimony that he did not read the July 1996 Lunar News article in September 1996, credible. Likewise, the Court does not find Teva's assertion that Dr. Yates should have read the article that was attached to the agenda at the May 1997 meeting, probative of Dr. Yates' intent to deceive because attendees, including Dr. Mazess, did not recall whether the once-weekly dosing concept was specifically addressed at the meeting. (Mazess Dep. at 180:19-181:7; Beckman Dep. at 131:1-23; Magri Dep. at 105:7-25; Sherwood Dep. at 146:17-23, 147:11-148:3). Further, the Court finds that even if once-weekly dosing was discussed at the meeting, the focus of the discussion was more likely than not centered on the April 1997 edition of the Lunar News, which was disclosed to the examiner, rather than the July 1996 edition because the April 1997 edition came out in the month preceding the meeting.

"In a case involving an omission of a material reference to the PTO, there must be clear and convincing evidence that the applicant made a deliberate decision to withhold a known reference." Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998). The Court concludes that Teva has proffered insufficient evidence of an intent to deceive on the part of Dr. Yates. Accordingly, the Court cannot conclude that Dr. Yates engaged in inequitable

conduct before the PTO by failing to disclose material prior art.

Conclusion

For the reasons discussed, the Court concludes that Teva has not proven that the patent-in-suit is invalid or that Merck engaged in inequitable conduct before the PTO.

An appropriate Order will be entered.

No. 05-236

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IN THE

Supreme Court of the United States

MERCK & CO., INC.,

Petitioner,

—v.—

TEVA PHARMACEUTICALS USA, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION FOR TEVA PHARMACEUTICALS USA, INC.

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RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, respondent states that the following companies own 10 percent or more of its stock: Overt UK, Ltd., Teva Pharmaceuticals Europe B.V., and Teva Pharmaceutical Industries Ltd.

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INTRODUCTION

From the filing of the complaint in the district court, through trial, appeal and in its petition for a writ of certiorari, Merck has yet to identify a single contribution its U.S. Patent 5,994,329 made to "science and the useful arts." U.S. Const., art. 1, § 8, cl. 8. Recognizing that Merck's patent added nothing to the art, the Federal Circuit held that claims 23 and 37 are invalid because they merely restated what a prior author had disclosed to the medical community long before the Merck inventors made their invention. The full court declined to hear the case *en banc*. Merck's petition seeks review of three unrelated questions. The Federal Circuit correctly addressed all three, following its own and this Court's precedents, and none presents an issue of significance to the public or to industry. Merck's petition should be denied.

RESPONDENT'S STATEMENT OF THE CASE

The '329 patent claims a method of administering a well known drug commonly referred to by its generic name "alendronate" and by Merck's trade name "Fosamax." The complete name for alendronate is "alendronate monosodium salt trihydrate," and the compound is a particular salt of alendronic acid. When introduced in 1995, alendronate was administered as a 10 mg tablet once daily for the treatment of osteoporosis, a 5 mg tablet once daily for prevention of osteoporosis, and a 40 mg tablet once daily for treatment of a rare condition called Paget's disease of bone. All three dosage strengths were formulated on an alendronic acid basis, *i.e.*, the amount of alendronate in the tablet was enough to provide as many molecules of the stated amount (*e.g.*, 10 mg) of alendronic acid, from which the salt was derived. Thus, for example,

the 10 mg dose actually contained 13.05 mg of alendronate, reflecting the higher molecular weight of the salt compared to that of alendronic acid.

The invention claimed in the '329 patent is a method of treating or preventing osteoporosis by administering alendronate in the form of a "unit dose" once per week instead of once per day. Claim 23 specifies that the amount of alendronate in this once-weekly dose is proportionally scaled up from the daily dose: "about 70 mg" instead of 10 mg, "on an alendronic acid basis."[1]

This controversy arose when Teva filed a "paragraph IV" certification that its marketing of a proposed generic equivalent to Merck's once-weekly form of Fosamax would not infringe the '329 patent or that the patent was invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Merck filed suit against Teva in the District of Delaware, and Teva defended primarily on the ground that the asserted claims were invalid because the subject matter they covered was unpatentable in view of the prior art.

At trial, Merck conceded that long before it filed the application for the '329 patent those skilled in the art recognized that preclinical and clinical evidence had established that alendronate would effectively treat and prevent osteoporosis if administered less frequently than once per day at a dose proportionally higher than the daily dose. In particular, in July 1996, a vendor of bone densitometry equipment, Lunar Corp., published an issue of

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[1] The issues are the same for both claims, and Teva will refer only to claim 23, which specifies a 70 mg dose for treatment of osteoporosis.

its quarterly newsletter, the *Lunar News*, which stated that alendronate could be administered for the treatment of osteoporosis once per week at a dose of 80 mg. The article also noted the dosing difficulties associated with alendronate (*see* Pet. 9), and pointed out that these difficulties could be ameliorated by the once-weekly regimen. The article ended with a long list of technical references, many of which Merck's inventors later cited in the '329 patent. (C.A. App. A3677-78).

Merck conceded that everything in the *Lunar News* article was scientifically sound. Moreover, the evidence was undisputed that the 80 mg dose specified in the article represented approximately seven times the daily dose, and that Dr. Richard Mazess, the author of the *Lunar News*, had specified 80 mg instead of the more intuitive 70 mg because the 80 mg dose could conveniently be administered as two of the commercially available 40 mg tablets normally dispensed for Paget's disease.

Merck never disputed that the *Lunar News* article is "prior art" with respect to claims 23 and 37 of the '329 patent. In attempting to distinguish its claims from the *Lunar News*, Merck asserted that the '329 patent defined "about 70 mg, on an alendronic acid basis," contrary to its ordinary definition, to mean "exactly 70 mg, on an alendronic acid basis." For that reason, according to Merck, the *Lunar News* did not precisely "describe" the invention as required for a showing of "anticipation" under 35 U.S.C. § 102(a).

Merck conceded, however, that persons skilled in the art recognized that the appropriate weekly dose would be seven times the daily dose, *i.e.*, 70 mg weekly for treatment. (App. 84a; C.A. App. A643-44). Thus, the slightly different dosage strength mentioned in the *Lunar*

News by itself was not enough to shield the claims from a challenge that their subject matter "would have been obvious" to those skilled in the art who read the *Lunar News* disclosure. *See* 35 U.S.C. § 103(a). Merck therefore further argued that the *Lunar News* disclosure should be disregarded, not because it was unscientific and not because it did not teach the once-weekly administration of alendronate claimed in the '329 patent, but because doctors would have been reluctant to recommend the administration of a weekly dose of seven times the daily amount. According to Merck, this reluctance would have stemmed from a perception that the larger dose would unacceptably exacerbate the gastrointestinal irritation occasionally associated with patients' failure to take alendronate tablets correctly.

Merck's petition reiterates and inflates these claims of medical skepticism. First, Merck states that its inventors had their idea in 1996, but that it went nowhere because of internal rejection at Merck. This contention is contrary to Merck's stipulation at trial that the invention date was more than a year later, long after the relevant *Lunar News* article circulated within the Merck research organization. (C.A. App. A92-93). Merck further falsely states that Teva's expert shared this skepticism, referring to that witness's testimony about a different side effect of a different drug. Finally, Merck cites to the animal studies recorded in the patent as the key to overcoming this skepticism. Its own expert, however, stated that these studies were irrelevant to human experience, the district court never relied on them, and the Federal Circuit correctly noted that they were "discredited at trial." (App. 19a).

The district court nevertheless accepted both Merck arguments. First, it held that "about 70 mg. on an alendronic acid basis" means "exactly 70 mg. on an

alendronic acid basis," and that 80 mg mentioned in the *Lunar News* is therefore not the "same" as "about 70 mg." The court also found that the perception of the likelihood of an increased incidence of gastrointestinal side effects would have deterred doctors from following the *Lunar News* suggestion, notwithstanding that everything in it was scientifically sound. The court then made the unprecedented leap that because doctors would have been skeptical of the *first* person to disclose the invention (Dr. Mazess), the *second* person (Merck) was entitled to a patent on it, even though that the second person contributed no additional insights to the concept. The district court justified removing Dr. Mazess's teaching from the public domain and awarding it to Merck as a 20-year monopoly on the grounds that Dr. Mazess received a Ph.D. degree in a discipline not directly related to the treatment of bone disease and that his publication – just like Merck's patent – was not "peer-reviewed." (App. 90a).

The Federal Circuit rejected both the district court's holdings. It first considered the claim construction issue. Following its own precedents, it stated that a construction of "about 70 mg" that is inconsistent with its ordinary meaning of "approximately 70 mg" must find clear support in the patent specification. It then noted that the textual passage that forms the sole basis for Merck's argument is at best ambiguous. Furthermore, the remainder of the text of the patent, including its claims, required that the term "about 70 mg" be accorded its ordinary meaning of "approximately 70 mg," because otherwise it would contain nonsensical redundancies. Critically for this petition, however, the Federal Circuit pointed out, as Merck had already conceded, that persons skilled in the art would have recognized 70 mg as the appropriate dose in any event. Thus, the claimed regimen would have been obvious under

either of Teva's or Merck's proposed constructions. (App. 16a n.10).

With respect to the district court's unprecedented nullification of the prior art, the Federal Circuit accepted the district court's factual finding that physicians would have been wary of Dr. Mazess's disclosure. (App. 19a). The court, however, held that this fact is irrelevant. First, the court held that whether the *Lunar News* included data sufficient to assuage physicians' concerns is not pertinent, particularly because the '329 patent includes no such data either. Second, the Federal Circuit noted that Dr. Mazess, despite his educational background, was indisputably highly qualified, whether or not he met the formal definition of a person skilled in the art. (App. 20a). Moreover, the record made clear that the *Lunar News* was widely known in the relevant community. Both Merck's and Teva's experts read it regularly, and the July 1996 issue was in fact circulated within Merck's research organization, making its way to the desk of the principal inventor almost a year before he filed for the '329 patent. (App. 97a).

The Federal Circuit held that the district court had erred in considering facts such as where the prior art author went to school and that his publication was not peer-reviewed. When these considerations were stripped away, then at best for Merck the only difference between what is claimed in the patent and what is disclosed in the prior art is the dosage strength: "about 70 mg" per week in the patent vs. "80 mg" per week in the prior art. The court noted that Merck had never contended that this difference was significant, particularly in view of its principal inventor's admission that persons skilled in the art would have recognized 70 mg per week as the appropriate dose. (App. 17a, 20a-21a).

Finally, the Federal Circuit discounted the district court's reliance on "commercial success." (App. 22a-24a). It noted that at all relevant times Merck was the only entity permitted to market alendronate in *any* dosage regimen, having a "new chemical entity" exclusivity as well as another patent that precluded any possible competition until at least 2008. The court reasoned that commercial success can be an indicium of patentability because it shows that notwithstanding the market incentives to make the patented invention, others did not do so before the inventor, so that the invention must not have been obvious to them. In this case, however, because at all relevant times Merck had a legal exclusivity for alendronate, market forces could not provide incentives to others, because they would know that no marketing outlet was available.

Judge Rader dissented. (App. 26a-27a). His dissent, however, focused exclusively on the majority's claim construction, arguing that the court should have accepted the district court's interpretation of "about 70 mg." The dissent did not urge a different outcome for the case, nor did it take issue with the majority's treatment of "commercial success."

The full court denied Merck's petition for *en banc* review. The three dissenters from the order denying the petition would have heard the case *en banc* solely on the issue of the panel's treatment of commercial success.[2] Thus, of the court's eleven participating judges, only one at

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[2] Chief Judge Michel's position on Merck's petition for rehearing *en banc* is not clear. Although he joined the dissent, he is not listed among the judges who "would rehear the appeal *en banc*." (App. 37a).

any time expressed disagreement with the panel's claim construction (Merck's first question), none found fault with the panel's treatment of the district court's fact finding on the merits (Merck's second question), and three questioned the panel's analysis of commercial success (Merck's third question).

REASONS FOR DENYING THE WRIT

I. THE COURT SHOULD NOT CONSIDER MERCK'S "ABOUT" CLAIM CONSTRUCTION ISSUE

A. Merck's First Question is Moot

Merck's proffered construction of claim 23 asserts that "*about* 70 mg, on an alendronic acid basis" does not mean what it says. Instead, according to Merck, it means "*exactly* 70 mg, on an alendronic acid basis." First, correct or not, the argument about the Federal Circuit's interpretation is pointless. The court made clear that although it believed that the district court's construction was erroneous, even under that construction the claims would be invalid:

> It makes no difference to this conclusion whether the court begins with the claim construction set forth by the panel or by the dissent [*i.e.*, by Merck]. In either case the district court erred in finding the '329 patent was not invalid. . . .

(App.16a n.10).

Merck's only response to the Federal Circuit's statement is to say that it was made "defensively" (Pet. 23 n.14), yet Merck's petition fails to articulate how adopting its proposed interpretation could possibly change the result. Indeed, the Federal Circuit's observation is entirely

consistent with Merck's admissions in the case. Merck's principal inventor admitted that persons skilled in the art would have recognized that 70 mg was the appropriate weekly dose because it is seven times the daily dose. Further, Merck conceded that persons skilled in the art would have recognized that the 80 mg dose referred to in the *Lunar News* was chosen only because it represents two tablets of the 40 mg dose that was available in the marketplace for the treatment of Paget's disease. In other words, the difference between exactly 70 mg, which Merck claims is specified in the patent, and 80 mg, specified by the *Lunar News*, is not a distinction that could make Merck's invention unobvious.

Thus, Merck's entire effort is an exercise in futility. This Court should not consider and decide issues that can have no effect on the outcomes of the cases in which they arise. *St. Pierre v. United States*, 319 U.S. 41 (1943) (petition for certiorari that raised "important questions" dismissed because resolution of them would not affect the rights of the litigants).

B. The Federal Circuit Correctly Interpreted the Claims

In construing the claims of the '329 patent, the Federal Circuit followed its own precedent that an interpretation of a term in a patent claim that is contrary to its ordinary meaning must be "clearly expressed" in the patent specification. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 866 (Fed. Cir. 1997). This approach has long been a part of the Federal Circuit's analytical framework, and Merck does not suggest that this Court should overrule it. Merck, however, fails to

address how following that methodology should have yielded a different result.

First, Merck does not dispute that the ordinary meaning of "about 70 mg" is "approximately 70 mg." Merck thus recognizes that it must find in the patent text a clear expression of the construction it proposes, *i.e.*, a construction exactly contrary to that ordinary meaning. As it did in the district court and in the Federal Circuit, Merck mischaracterizes the passage of the patent specification on which it relies to provide that interpretation. In particular, it states that the passage is a "definition" of "about 70 mg." It is not. The key sentence does not say "about 70 mg. . .on an alendronic acid basis. . *means* exactly 70 mg, on an alendronic acid basis." Instead, it states that "about 70 mg. . .on an alendronic acid basis . . . is *calculated based on* 70 mg of alendronic acid." In other words, to normalize the dosage of various possible salts of differing molecular weights, the weight of the compound used is that necessary to provide the same number of molecules as the stated amount of alendronic acid. The statement does not provide a definition of "about 70 mg" of any sort, much less a definition that eviscerates the ordinary meaning of the term. Instead, it states the basis on what it must be calculated: an equivalent amount of the corresponding acid.

This Court's precedents require that a patent claim be construed in the context of the entire patent document. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389 (1996) ("standard construction rule. . .[is] that a term can be defined only in a way that comports with the instrument as a whole."); *Bates v. Coe*, 98 U.S. 31, 38 (1878) (patent claim construed with reference to entire document). The Federal Circuit did so, and noted what the district court had ignored: Merck's proposed construction is at odds with the entirety of the rest of the patent text, and, most important,

makes nonsense out of the claims. In particular, in 15 different instances after the occurrence of the purported definition of "about [70] mg," the patent uses the phrase "about [70] mg, on an alendronic acid basis." (App. 14a-15a). If "about [70] mg" by itself meant, as Merck insists, "on an alendronic acid basis," then the latter part of the phrase is redundant. Although a single redundancy might be disregarded as a drafting error, a pattern of 15 raises more than a suspicion that the interpretation that creates the redundancy must be wrong. Similarly, under the district court's interpretation, the claims themselves would contain the same nonsensical redundancy. For example, recast per the district court, claim 23 would read:

> A method for treating osteoporosis in a human comprising orally administering *70 mg, on an alendronic acid basis, of alendronate monosodium salt trihydrate, on an alendronic acid basis*, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

(Emphasis added). Federal Circuit precedent, whose correctness Merck does not dispute, requires that an interpretation that creates a redundancy in a patent claim is disfavored compared to one that does not. *Electa Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000); *Gen. Am. Transportation Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed. Cir. 1996). Thus, the Federal Circuit carried out the claim construction task exactly as it should have: it noted the agreed upon "ordinary meaning" of the term, and examined whether the specification clearly expressed a contrary meaning. Noting that the proposed contrary meaning was inconsistent with the patent as a whole, it held that the specification as a whole therefore supported the ordinary meaning.

Merck's argument here is that the Federal Circuit, though charged with interpreting claims "as a matter of law," *Markman*, *supra*, must defer to the district court's construction in this case, even where that construction is inconsistent with the entirety of the remainder of the patent. According to Merck, the district court's construction involved "findings of fact," to which the Federal Circuit should be required to defer.

Although the issue of the deference that should be accorded a district court's subsidiary factual findings made in the context of construing a patent has created interest in the field, this case is not a vehicle for resolving it. First, as discussed above, it is moot. Second, the Federal Circuit claim construction exercise here did not reverse a finding of fact. That is, "about" is not a technical term, and its meaning to those skilled in the art was not the subject of any expert testimony that the district court credited. Indeed, as Merck notes, the district court did not accept Teva's witness's claim construction testimony, and no Merck witness offered any testimony with respect to the meaning of "about 70 mg."[3] Thus, the district court did not weigh the conflicting testimony of experts; it merely rejected the only testimony offered, and relied on its own examination of the patent. The Federal Circuit examined the same text as the district court, but recognized that the

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[3] The principal "testimony" on which Merck relies was Teva's expert's answer, "possibly," to the question posed by Merck's counsel:

> I understand, but it is what it says, and perhaps the person wanted to say if it's a certain salt one, you might use 71, and if it's a certain salt 2, you might use 73. Isn't that what's indicated by this?

district court had not done its job – it had ignored aspects that any document construction requires.

The district court's failure to construe the claims with the entire document in mind is not a finding of fact; it is an error of law. Even under a deferential standard, it was freely reviewable. For that reason, this case does not present the issue that Merck suggests should be addressed.

II. THE FEDERAL CIRCUIT GAVE APPROPRIATE DEFERENCE TO THE DISTRICT COURT'S FINDINGS OF FACT UNDER FED. R. CIV. P. 52(a)

Merck's second question, whether the Federal Circuit correctly applied Fed. R. Civ. P. 52(a), presents no issue whose resolution is applicable beyond this case. This Court has already carefully defined the appellate role in reviewing a district court's findings of fact, and Merck's petition does not suggest that any redefinition of that role is necessary. For that reason, the Court should not consider Merck's second question.

In any event, the Federal Circuit correctly applied Rule 52(a). In *Graham v. John Deere Co.*, 381 U.S. 1, 17, this Court defined the three essential factual inquiries in determining whether a patented invention "would have been obvious":

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of skill in the pertinent art resolved.

Here, the parties did not dispute any of these issues. With respect to the scope and content of the prior art, they agreed that persons skilled in the art would have understood that once weekly dosing of alendronate at seven times the daily

dose would be effective, that the *Lunar News* discloses dosing at approximately that level, and that the only reason it refers to "80 mg" instead of "70 mg" was the commercial availability of a 40 mg tablet. They agreed that the *Lunar News* articulates the same motivation for the once-weekly regiment as the '329 patent. They agreed on the definition of a person of ordinary skill in the art. Finally, they agreed that the only difference between the *Lunar News* and the claimed invention, even accepting the district court's claim interpretation, was the precise amount (80 mg vs. 70 mg). The Federal Circuit noted that this difference is insignificant in light of the recognition that 70 mg would have been understood to be the appropriate dose. Thus, with respect to the only relevant factual issues, the parties, the district court and the Federal Circuit agree. There is nothing for this Court to review; the case presents no issue under Rule 52(a).

The key finding that Merck sought, which was the focus of its entire trial presentation, was that persons skilled in the art would have been skeptical of Dr. Mazess's *Lunar News* suggestion notwithstanding its medical and technical merit. The district court made that finding. The Federal Circuit did not reject it; indeed, as Merck is forced to admit, the Federal Circuit accepted it for the purposes of its analysis. (Pet. 25; App. 19a). Moreover, nowhere did the Federal Circuit reject the district court's findings that the *Lunar News* disclosures did not "overcome" medical skepticism, as Merck suggests.

With respect to Dr. Mazess, Merck falsely states that the Federal Circuit "elevated" his expertise "over all others." The court did no such thing. Dr. Mazess never testified at the trial. The court merely pointed out that Dr. Mazess had impressive credentials in the field, a fact that the record overwhelmingly makes clear and that Merck

does not dispute. Moreover, the Federal Circuit rightly noted what Merck also does not dispute: that the *Lunar News* circulated widely within the relevant community, including to Merck's principal inventor, and was read by both experts in the case.

The Federal Circuit's decision did not turn on the relative qualifications and credibility of Dr. Mazess and Merck's expert witness. Instead, it was based on a rejection of Merck's legal theory, *i.e.*, that a prior art publication that is scientifically sound and that subsequent events prove is correct can be nullified based on the credentials of its author. The court recognized that the finding of skepticism, even if supported, is not relevant to the issue of obviousness in this case because, as Merck does not dispute, its patent adds nothing to the *Lunar News* except the Merck name and the academic credentials of its inventors. Under the circumstances, the Federal Circuit held, appropriately, that a second-comer (here, Merck's physician-inventors) cannot obtain a patent on a concept placed in the public domain by someone else solely on the strength of a more prestigious educational experience. As the court stated:

> Indeed, to the extent the district court finds Merck's once-weekly dosing idea non-obvious, it still must explain why Merck and not Dr. Mazess should get credit for the idea.

(App. 21a).

The absurdity of Merck's argument is made plain by its implications. If Merck's inventors had written the *Lunar News* articles, and if Dr. Mazess had obtained the '329 patent, then under Merck's approach the patent would be invalid because the authors' credentials would lend to the publication a *gravitas* that Dr. Mazess's background could not. Similarly, if instead of publishing his idea in the

Lunar News, Dr. Mazess had applied for a patent on it contemporaneously with Merck, then the resulting "interference" proceeding (*see* 35 U.S.C. § 135) would not be decided on the basis of which was the first inventor as the statute requires, but instead on which went to what school.[4] No decision of this or any other court supports Merck's contention that the validity of a patent depends on a comparison of the resumes of the inventor and the prior art author.

The record shows that the Federal Circuit properly applied Rule 52(a). It did not base its decision on a rejection of district court fact findings. Instead, it rejected Merck's groundless legal theory. Recognizing that the determination of obviousness is ultimately a question of law, *Graham*, *supra*, *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1108 (Fed. Cir. 2003), it held that as a matter of law Merck's patent is invalid. This Court should not accept Merck's second question for review.

III. THE FEDERAL CIRCUIT CORRECTLY ANALYZED "COMMERCIAL SUCCESS"

The "commercial success" of an invention is a "secondary consideration" that "may have relevancy" to

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[4] Merck's rationale would require that the Wright brothers be deprived of credit for powered flight, the announcement of which was widely derided, because of their background as bicycle builders. Similarly, Albert Einstein should not be honored for many of his insights, which likewise were at first skeptically received, because he published them while employed not as a university professor, but rather as a mere examiner in the Swiss Patent Office.

whether the invention would have been obvious. *Graham*, *supra*. Whether or not a patented invention is commercially successful, however, the patent is "presumed valid." 35 U.S.C. § 282. Thus, a patentee need not rely on or prove commercial success to prevail against a challenge to the patent.

The rationale for considering commercial success is that it may show that a market demand existed for the patented invention, and that others with an incentive to meet that demand would have done so had the invention been obvious. *See* Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. Pa. L. Rev. 1169, 1175 (1964) (*cited in Graham*). *See also Chicago Rawhide Mfg. Co. v. Crane Packing Co.*, 523 F.2d 452, 459 (7th Cir. 1975), *cert. denied*, 423 U.S. 1091 (1976). As the Federal Circuit stated in this case:

> Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art.

(App. 23a). Conversely, if the market is foreclosed to everyone skilled in the art except the patent owner, then the fact that the patentee successfully marketed the invention can say nothing about whether it would have been obvious to others.

Here, the market was foreclosed to all except Merck. Because Merck was the first entity to bring alendronate to market (as a daily dose), it was entitled to a five-year exclusivity, beginning in 1995, for that compound for any pharmaceutical use at any dose. 21 U.S.C. § 355(c)(3)(D)(ii). In addition, Merck had another patent that broadly protected alendronate, excluding everyone else

from the market until 2008.[5] Thus, the commercial success of once-weekly administration of alendronate, even if associated with its advantages compared to the once-daily regimen, is not necessarily attributable to its non-obviousness. Instead, it is just as easily attributable to the fact that all potential competition was foreclosed, so that no one could take up the suggestion of the *Lunar News* for almost 12 years after it was published.

Merck's petition does not dispute the Federal Circuit's stated rationale for considering commercial success. Nor does it dispute the essential fact: that in 1996 no other entity had the economic incentive to attempt to develop a once-weekly alendronate dose, since it would know that it could not market the product for more than a decade. Instead, Merck merely lifts from their contexts quotations from decisions of this and other courts. In none of those cases, however, were the circumstances analogous to those here. In all of them, those skilled in the art were free to compete with the patent owner and were free, if they had the insight, to exploit the patented concept. That they did not do so before the patentee was evidence that the invention was not obvious to them, and therefore would not have been obvious to the hypothetical person of ordinary skill in the art.

Merck complains that the Federal Circuit's decision "discriminates" against improvement patents, stating that a "third party" that patents an improvement can rely on its

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[5] Merck's statement of the issue, which refers only to "improvement patents," ignores the "new chemical entity" exclusivity. It represented an even higher barrier to potential competition than Merck's pre-existing patent because it was not subject to judicial challenge.

commercial success to bolster nonobviousness, but that the owner of the basic patent who likewise patents an improvement cannot. The situation Merck posits, however, will never arise. If, like potential third parties here, Merck's hypothetical third party is foreclosed from competing by the basic patent, it will have no commercial success on which to rely because any attempt to commercialize the improvement will be illegal and will be enjoined. On the other hand, if the improvement is not an infringement of the basic patent, the Federal Circuit's rationale and holding in this case will not apply because competition will not be foreclosed, and the success of any party's improvement invention, including that of the owner of the basic patent, may indeed be evidence that the improvement was not obvious.

The Federal Circuit's ruling may require rigorous analysis of commercial success and the substitution of rationality for the chanting of the "commercial success" mantra. This is a step forward, not a retreat. Commercial success of a patented invention shows that the invention was a good idea. It does not necessarily show that it was unobvious. Carrying an umbrella when the forecast calls for rain is a good idea, but not an unobvious one. Here, the commercial success of once-weekly dosing of alendronate shows that it was a good idea. It was, however, an idea of another, which only Merck could legally exploit. That Merck successfully did so shows nothing more than the fact that only Merck was in a position to do so.

As an afterthought, and in tacit recognition of the force of the Federal Circuit's reasoning, Merck argues that "incentives" in fact existed, referring to the "safe harbor" of 35 U.S.C. § 271(e)(1), which permits otherwise infringing activity if carried out in order to generate data for submission to the FDA, and to speculation about Teva's

activities with respect to alendronate. At trial, however, when it should have addressed the issue with evidence, Merck did not do so. Nothing in the record provides insight into Teva's plans, incentives or the economics of Teva's business model.

Merck's real lament is that even though it had the burden of proof on the issue, it offered no evidence at trial that incentives still existed for those skilled in the art to develop the solutions of the '329 patent notwithstanding the insurmountable barriers to entry created by Merck's patent and statutory exclusivities. Merck in essence asks this Court to write a rule of law that would excuse its failure to prove the necessary facts. This Court should recognize that the Federal Circuit correctly held that under the circumstances of this case, the commercial success of once-weekly alendronate is not probative of the unobviousness of the invention claimed in the '329 patent. For that reason, the Court should not accept Merck's third question for review.

CONCLUSION

Merck's '329 patent is invalid because it claims a concept completely described in the prior art. Merck's petition presents no question worthy of this Court's attention. It should be denied.

September 16, 2005 Respectfully submitted,

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No. 05-236

In the Supreme Court of the United States

MERCK & CO., PETITIONER,

v.

TEVA PHARMACEUTICALS USA, INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMICUS BRIEF OF THE PROCTER & GAMBLE COMPANY SUPPORTING PETITIONER

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September 22, 2005

QUESTION PRESENTED

Amicus asks the Court to grant review on the third question presented in the petition, which amicus casts as follows:

Under 35 U.S.C. § 103(a), a patent may not issue if the differences between the claimed invention and the prior art are such that, at the time the invention was made, the invention would have been "obvious" to a person having ordinary skill in the art to which the invention pertains.

The question presented is whether 35 U.S.C. § 103(a) allows a court to consider the commercial success of an improvement patent in determining whether, at the time the invention was made, the invention would have been "obvious" to a person having ordinary skill in the art.

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INTEREST OF AMICUS[1]

Amicus Procter & Gamble is a large, multi-national company that markets over 300 branded products, including numerous pharmaceutical products. Procter & Gamble holds many patents, the majority of which are improvement patents. Procter & Gamble is a licensee of Merck's U.S. Patent No. 5,994,329. Procter & Gamble has a strong interest in ensuring that the law with respect to improvement patents is clear.

STATEMENT

An "improvement" patent is a patent that builds directly on the teachings of a prior patent. In this case, for example, Merck's U.S. Patent No. 4,621,077 (the " '077 patent") discloses the administration of alendronate as a treatment for osteoporosis. Merck's U.S. Patent No. 5,994,329 (the " '329 patent") is an "improvement" patent that Merck obtained on the prior '077 patent. The '329 patent is an improvement over the '077 patent because it discloses the administration of a higher dose of alendronate on a weekly basis, which increases compliance but does not increase adverse gastrointestinal events.

1. Osteoporosis – or porous bone – "is a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased risk of fractures of the hip, spine, and wrist." National Institutes of Health, *Osteoporosis Overview*, at 1 (June 2005), *available at* http://www.osteo.org/inetdocs/r106pi.pdf. The National Institutes of Health have labeled the disease "a major public health threat" for

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[1] Letters of consent have been lodged with the Clerk. No counsel for a party authored any part of this brief. Amicus or its counsel will bear all costs associated with this brief.

more than 44 million Americans and estimate that the disease directly incurs national expenditures of $14 billion a year. *Id.*

The human body is constantly removing old bone and replacing it with new bone. Removal of old bone is called "resorption"; replacement with new bone is called "formation." Until about age 30, bone formation outpaces bone resorption. Then, bone resorption slowly begins to exceed bone formation. Osteoporosis will develop "when bone resorption occurs too quickly or when replacement occurs too slowly." *Id.* at 2.

2. For many years, pharmaceutical manufacturers have sought to develop medicines to treat osteoporosis. Petitioner Merck has centered its work on a compound that inhibits bone resorption. The compound is alendronate, one of a family of drugs known as bisphosphonates. In 1986, Merck obtained the '077 patent on the use of alendronate. Merck markets the compound under the brand name Fosamax.

Merck's Fosamax is one of four prescription drug products available in the United States whose primary indication is for the treatment of osteoporosis. The others are Novartis' Miacalcin, Eli Lily's Evista, and Procter & Gamble's Actonel, which is based upon a bisphosphonate called risedronate. (Together these four drugs are known in the industry as "FAME," for the first letters of the products Fosamax, Actonel, Miacalcin and Evista.) Other pharmaceutical companies were attempting to develop bisphosphonate-based osteoporosis treatments or were marketing other bisphosphonate-based treatments outside the United States.

In 2000, Merck introduced its high-dosage once-weekly Fosamax product, the use of which is claimed in the '329 patent that is the subject of this action. Once-weekly Fosamax was an immediate success. Within six

months of its launch, the once-weekly tablets became the most prescribed drug in the FAME market.

3. In this litigation Teva has argued Merck's invention, once-weekly dosage Fosamax, would have been obvious to one of ordinary skill in the art and that the claims of the '329 patent are, therefore, invalid. At trial, Teva offered evidence of two articles from a prior art publication, *Lunar News*, both of which were entitled "Update: Bisphosphonate." One of the two articles suggested that "[t]he difficulties with oral bisphosphonates may favor their episodic (once/week) or cyclical (one week each month) administration." In addition to mentioning the possibility of once-weekly administrations of alendronate, it also specifically suggested the intravenous administration of another bisphosphonate – ibandronate – as a solution to the difficulties associated with daily dosing of bisphosphonates.

One of Merck's responses to this argument was that the fact of weekly Fosamax's success is relevant to show its claimed invention would not have been obvious. The parties offered evidence relating to this issue, including evidence on what was driving the Fosamax sales. Merck introduced evidence showing that others, including Procter & Gamble, had an opportunity and incentive to develop an improved dosage form. As Judge Farnan noted in his post-trial decision, one of the arguments Teva advanced in response to this evidence was that Merck's commercial success was irrelevant because Merck was the only entity allowed under the '077 patent to market alendronate tablets. Merck responded to Teva's argument by noting that, while it held the '077 patent, its evidence of commercial success was relevant in light of Procter & Gamble's opportunity and incentive to develop a weekly dosing form of Actonel. Judge Farnan focused his analysis on once-weekly Fosamax's "effects on the osteoporosis

market in general" (App. 92a), implicitly rejecting Teva's argument.

4. On appeal, the majority of the court noted:

> Although commercial success might generally support a conclusion that Merck's claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the *Lunar News* articles.

(App. 23a-24a.) The majority then ruled that:

> Financial success is not significantly probative of that question in this case because others were legally barred from commercially testing the *Lunar News* ideas.

(App. 24a.)

The Federal Circuit denied Merck's petition for rehearing *en banc*. In dissent, Judge Lourie, joined by Chief Judge Michel and Judge Newman, argued that rehearing was warranted because the panel majority's ruling effectively held commercial success irrelevant in considering the obviousness of an improvement patent:

> The panel's rule is especially unsound in the context of an improvement patent, as here, because it holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention.

(App. 38a-39a (Lourie, J., dissenting).)

The dissenters concluded by noting that the panel's opinion "creates" a "confusion in the law." (App. 39a (Lourie, J., dissenting).)

REASONS FOR GRANTING THE WRIT

The Court should grant review because the rule announced by the Federal Circuit threatens to inhibit innovation by making improvement patents more difficult to defend as nonobvious and therefore more risky to pursue. Whether the rule is valid has especially large implications for innovations in medicine in view of the enormous resources devoted by pharmaceutical manufacturers and biotech companies to improving on previously patented medicines. Because the Federal Circuit is the only court of appeals that can decide questions of patent law, and because that court has denied *en banc* review of the panel's decision, only this Court can now resolve the important question of patent law presented.

The commercial success of an invention is normally considered an indication that the invention was not "obvious." The theory is that an invention's commercial success reflects a market demand that, had the invention been obvious, would have led others to try to develop the invention themselves. Here, the Federal Circuit concluded that commercial success has no significance in the case of an improvement patent because no one but the holder of the basic patent could legally have marketed the protected invention.

This rule defines the relevant market too narrowly. In the case of an improvement patent, the relevant market is not necessarily the market for that particular invention. Instead, the relevant market may be the market for inventions of the same general character that would meet the same need. Where, as here, there is evidence that others had the opportunity to develop other ways to skin the same cat, the fact that only the holder of the prior patent could skin the cat with his particular invention does not make the success of his invention irrelevant to its obviousness.

This Court has long recognized that commercial success is a consideration in determining whether an invention merits patent protection: "The utility of the change, as ascertained by its consequences, is the real practical test of the sufficiency of an invention; and since the one cannot exist without the other, the existence of the one may be presumed on proof of the existence of the other." *Smith* v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876).

Under 35 U.S.C. § 103(a), a patent may be challenged on the ground that it was "obvious" in light of prior art. This Court has held that the commercial success attendant to the introduction of the invention is "relevant" in determining the obviousness of a patent, at least if the success results from the utility of the invention and not some other factor. *Graham* v. *John Deere Co.*, 383 U.S. 1, 17-18 (1966). As the Federal Circuit explained in this very case: "Commercial success is relevant [to obviousness] because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." (App. 23a.)

For this reason, the Federal Circuit has long recognized that "the public and commercial response to an invention is a factor to be considered in determining obviousness, and is entitled to fair weight." *Arkie Lures, Inc.* v. *Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997). As far as amicus is aware, that court – until now – had consistently *required* district courts to consider evidence of the commercial success of an allegedly obvious innovation. *See, e.g., Ruiz* v. *A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000). The court recognized not only that "[c]ommercial success is * * * a strong factor favoring nonobviousness," *Akzo N.V.* v. *U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1481 (Fed. Cir. 1986), but also that such

objective indicia of nonobviousness as commercial success "may often be the most probative and cogent evidence in the record," *Stratoflex, Inc.* v. *Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

The decision of the panel majority – in effect holding that commercial success has no relevance in considering the obviousness *vel non* of an improvement patent – is a sharp break with such precedent, sowing "confusion in the law." (App. 39a (Lourie, J., dissenting).). Because "most inventions represent improvements on some existing article, process, or machine," *Gen. Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 368 (1938), the confusion sowed by the panel majority's decision is bound to inhibit innovation. Intervention by this Court is warranted to clarify the law.

The court of appeals held that "[f]inancial success is not significantly probative of [obviousness] in this case because others were legally barred from commercially testing the *Lunar News* ideas." (App. 24a.) However, the *Lunar News* articles spoke of episodic or cyclical administration of bisphosphonates, specifically mentioning not only Merck's alendronate but also Boehringer Manheim's ibandronate-based treatment. It simply does not follow from the existence of Merck's patent on its original alendronate formulation that no one else could legally have developed a safe and effective weekly dosing regimen of a bisphosphonate as a treatment for osteoporosis. The commercial incentive to do so was there; the fact that only Merck did so is an indication that a once-weekly bisphosphonate dosing regimen was not "obvious" at the time Merck obtained the '329 patent.

Indeed, as Merck sought to show at trial, Procter & Gamble itself had incentive and opportunity to develop a once-weekly dosing form of Actonel, a daily bisphosphonate-based osteoporosis treatment. (App. 82a.) Further-

more, the record also indicates that numerous other bisphosphonate-based osteoporosis treatments were being developed and/or marketed outside the United States by other pharmaceutical companies, each of which had the opportunity and incentive to bring to the U.S. market a weekly-dosing treatment.

The point is not that the panel majority failed to give this evidence due weight, but that the panel majority ruled such evidence *irrelevant* when an improvement patent is involved. The Federal Circuit considered it beside the point whether *Lunar News* taught other ways to skin the cat – *i.e.*, other ways to meet the need for a once-weekly bisphosphonate dosing regimen.

But the commercial success achieved by once-weekly Fosamax did not reflect a market need for once-weekly *Fosamax*; it reflected a market need for osteoporosis treatments. Merck's alendronate-based treatment represented but one approach to a problem that many pharmaceutical companies were simultaneously attempting to address in different ways, as the district court recognized in focusing its analysis on once-weekly Fosamax's success in "the osteoporosis market in general," and in finding evidence of commercial success in the fact that Fosamax quickly "became the most prescribed drug in the FAME market." (App. 92a.)

The court of appeals, on the other hand, inappropriately narrowed its field of inquiry by focusing only on Merck's ability, based upon the '077 patent, to preclude others from producing an alendronate-based osteoporosis treatment. This ability, however, did not confer upon Merck a monopoly in the osteoporosis treatment market. Just as Merck was attempting to improve on once-daily Fosamax, its FAME competitors – including Procter & Gamble – were engaged in efforts to improve on their treatments – including Actonel.

The court of appeals may well have been correct when it observed that the rationales underlying treating commercial success as an indicium of nonobviousness tie it "directly to the practical, financial source of impetus for research and development." (App. 23a.) However, it is incorrect that "that chain of inferences fails on the[] facts" of this case. (*Id.*) Merck had an incentive to attempt to move to weekly dosing of Fosamax: had one of its competitors introduced a weekly-dosing form of another bisphosphonate, it would have lost considerable ground in the osteoporosis treatment market.

Unfortunately, the rule announced by the court of appeals, rooted in its erroneous conception of the appropriate market, will itself "fail on the facts" of nearly every case involving improvement patents. As this Court has noted, "most inventions represent improvements on some existing article, process, or machine." *General Electric Co.*, 304 U.S. at 368. And in the vast majority of cases involving improvement patents, they will represent but one means of meeting an existing market need. For this reason, a rule, under which "commercial success for an improvement is irrelevant when a prior patent dominates the basic invention" (App. 39a (Lourie, J., dissenting)), would have wide-reaching deleterious effects. Holders of existing patents will confront unique and unjustifiable burdens in defending improvement patents as part of their efforts to remain competitive. And this, in turn, will diminish their incentive to continue innovating.

In short, the rule announced by the court of appeals undermines the fundamental rationale underlying the patent system: to encourage innovation. The real world consequences of the court of appeals' conceptual error are enormous. The decision of the court of appeals unjustifiably forecloses holders of improvement patents from relying on the important evidentiary tool of commercial suc-

cess in defending their patents from claims of invalidity. The Court should grant the writ in this case to ensure that innovators are not discouraged by the legal system from investing in valuable improvements on their existing products.

CONCLUSION

For the reasons stated, review of the third question presented in the petition should be granted.

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IN THE

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TEVA PHARMACEUTICALS USA, INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONER

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IN THE

Supreme Court of the United States

No. 05-236

MERCK & CO., INC.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONER

INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the nation's leading pharmaceutical research and biotechnology companies.[1] In 2004, PhRMA's members "invested an estimated $38.8 billion" in the discovery and development of new medicines. PhRMA,

[1] Letters from counsel for both parties consenting to the filing of this brief have been submitted to the Clerk. No counsel for a party authored any part of this brief, and no person or entity other than members of or counsel for PhRMA made a monetary contribution to the preparation or submission of this brief. Although petitioner Merck & Co., Inc. is one of PhRMA's more than thirty members (the names of all of which are available at http://www.phrma.org/whoweare/members/), petitioner did not contribute to the funding or drafting of this brief.

Pharmaceutical Industry Profile 2005—From Laboratory to Patient: Pathways to Biopharmaceutical Innovation 2, *available at* http://www.phrma.org/publications/publications//2005-03-17.1143.pdf. The societal benefits from such investment are undeniable. "New medicines generated 40 percent of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000." PhRMA, *Pharmaceutical Industry Profile 2004—Focus on Innovation*, at VII. "Since 1990, pharmaceutical research company scientists have invented and developed more than 300 completely new medicines, vaccines, and biologics approved by the Food and Drug Administration . . . ." *Id.* at 10.

PhRMA's members appreciate the importance of innovation—whether fundamental or incremental—to technological progress and social well-being. They also have an intimate appreciation of the importance of patent rights. In an industry where research and development is expensive and competition is fierce, strong patent protection is necessary for PhRMA's members to be able to recoup the costs of their investments. *See* Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in *Science and Cents: Exploring the Economics of Biotechnology* 87, 88-92, 99-101 (John V. Duca & Mine K. Yücel eds., 2003), *available at* http://www.dallasfed.org/research/pubs/science/index.html. The Federal Circuit's decision in this case significantly undermines confidence in the ability of innovators to obtain and enforce patents on improvements and thereby substantially threatens the pace of continued innovation in the pharmaceutical industry.

STATEMENT

Petitioner Merck owns both the patent in suit (the '329 patent) and an earlier patent (the '077 patent). Pet. App. 2a, 24a, 44a-45a. The '077 patent claims a method of preventing or treating osteoporosis through the oral administration of alendronate. Merck secured approval from the Food and Drug Administration to market an alendronate preparation called Fosamax® for use in 5 or 10 milligram daily doses.

While effective, this daily regimen in practice led to gastrointestinal side effects in some patients. The '329 patent claims an improved method consisting of using 35 or 70 milligram doses of alendronate once a week. *Id.* at 3a-4a. The patent disclosure explains that, counter-intuitively, the increased dosage at more widely-spaced intervals leads to a pronounced reduction in the incidence of related gastrointestinal distress.

The dosing improvement was a commercial as well as a medical success. Pet. App. 22a-23a, 91a-93a. The '329 patent issued in 1999, and Merck obtained approval of 35 and 70 milligram doses in 2000. *Id.* at 44a, 92a. Commercial release of the corresponding new products was followed by both a sharp increase in the rate of sales growth for Fosamax® and a 10% jump in petitioner's share of the primary market for osteoporosis-treating drugs. *Id.* at 92a-93a.

In October 2000, respondent Teva sought FDA approval to market generic copies of Merck's weekly-dose Fosamax®. Pet. App. 4a, 44a. Merck filed suit under 35 U.S.C. § 271(e)(2)(A), arguing that sale of Teva's copies would infringe the '329 patent.[2]

Teva stipulated that sale of its proposed weekly-dose products would infringe the '329 patent, but Teva challenged the patent's validity and enforceability. Pet. App. 46a. Among other things, Teva argued that Merck's improvement claims were invalid because the claimed weekly-dosing regimen "would have been obvious at the time the invention was made to a person having ordinary skill in the art," 35 U.S.C. § 103(a). Teva relied in particular on two alleged prior-art references in an equipment manufacturer's newsletter, the *Lunar News*. These references suggested the possibility of using once-weekly doses (although in amounts different from the 35 and 70 milligram amounts recited in the '329 patent).

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[2] In a separate suit, Teva's application for approval of a generic drug for daily use was found to infringe the '077 patent. Pet. App. 5a n.3.

After trial, the district court rejected Teva's obviousness argument. Pet. App. 73a-94a. In analyzing "secondary considerations" favoring a finding of nonobviousness, the district court concluded that Merck had shown both commercial success and a nexus between that success and the patented improvement. Pet. App. 91a, 93a. The court accordingly weighed commercial success along with other factors in concluding that Teva had not borne the burden of "prov[ing] by clear and convincing evidence that the '329 patent was obvious in light of prior art." *Id.* at 93a-94a.

The Federal Circuit reversed, holding the relevant claims "invalid as obvious." Pet. App. 25a. The court did not question the district court's factual findings that once-weekly Fosamax® was commercially successful and that there was a causal "nexus" between that success and the improvement claimed by the patent. *Compare id.* at 22a-24a *with id.* at 91a-93a. It held instead that the improvement's commercial success was not probative in this case. *Id.* at 23a-24a. To justify that holding, the court first tied the relevance of an invention's commercial success to the distinct question whether previous attempts to solve a problem "have been made and have failed." *Id.* at 23a (internal quotation marks omitted). It then reasoned that commercial success said nothing significant about whether Merck's invention was "non-obvious in relation to the ideas set forth in the *Lunar News* articles" because, in the court's view, Merck's earlier '077 patent and additional exclusive rights under the Federal Food, Drug, and Cosmetic Act meant that "others were legally barred from commercially testing the *Lunar News* ideas." *Id.* at 24a.

Merck petitioned for a panel rehearing and a rehearing en banc. In an opinion dissenting from the denial of rehearing en banc, Chief Judge Michel and Judges Lourie and Newman agreed that the panel's decision "erred in linking commercial success to the failure of others" and in "conclud[ing] that commercial success is not probative because 'others were legally barred' from commercially testing certain ideas." Pet. App. 38a. In their view, "the full court

should have reheard the appeal to eliminate the confusion in the law that the panel opinion creates." *Id.* at 39a.

SUMMARY OF ARGUMENT

An invention is not patentable if, at the time it was made, the claimed innovation would have been "obvious" to one of ordinary skill in the relevant art. It has long been settled law that evidence of an invention's commercial success is an independent "secondary consideration" tending to show that the invention was not obvious. *See, e.g., Graham* v. *John Deere Co.*, 383 U.S. 1, 17-18 (1966). The Federal Circuit has now held to the contrary. According to the Federal Circuit's new rule, commercial success supports nonobviousness only by acting as evidence of *another* factor: "failure of others" to have produced the same invention. Pet. App. 23a-24a.

That holding departs from precedent, experience, and reason. For well over a century, courts have recognized that commercial success can evidence patentable innovation in ways quite distinct from "failure of others." Commercial success can, for example, show a neutral (and sometimes, as here, expert) marketplace's enthusiastic appreciation of an invention's distinctive qualities. It can also confirm that the invention responded to a long-felt need. Like the other "secondary considerations" this Court has identified, commercial success can, by itself, be an important "sign post[]" in a court's assessment of otherwise "misty" questions of patentability. *Reiner* v. *I. Leon Co.*, 285 F.2d 501, 503-504 (2d Cir. 1960) (L. Hand, J.), *cited in Graham*, 383 U.S. at 35-36. The Court should therefore reject a rule tying the probative value of commercial success to an inference of failure of others.

The Court should also review and reject the Federal Circuit's new rule that an invention's commercial success cannot help show nonobviousness if the invention is an improvement of an earlier invention for which the patent holder had pre-existing exclusive rights in the United States. Exclusive rights under U.S. patent or food and drug

laws do not—and, with respect to activity abroad, cannot—prevent third parties from competing in a "race to improve." The Federal Circuit's rule improperly favors third-party improvers over original innovators who initially disclose their inventions at an early stage (as patent law encourages) and then proceed to improve them. The Federal Circuit's rule thereby weakens the incentives to create and disclose both the initial invention and follow-on improvements, contrary to patent law's purpose of "promot[ing] . . . Progress." U.S. Const. art. I, § 8, cl. 8.

The Federal Circuit's holdings threaten harm extending far beyond the confines of this case. Three judges below rightly identified the need to address "the confusion in the law" that the court's opinion has created. Pet. App. 39a. A later case has already directed that the holdings below should govern commercial-success analysis whenever the "active ingredient" in a drug "was previously patented." *Syntex (U.S.A.) LLC* v. *Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005). Further, those holdings are not limited to pharmaceutical inventions, but will apply equally in all fields of technology, significantly complicating the law in ways that run counter to the reasons identified by this Court for referring to considerations such as commercial success. This Court should grant review and confirm that the commercial success of an improvement invention is an independent consideration in favor of nonobviousness, without regard to a patent holder's pre-existing rights.

REASONS FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT HAS DEPARTED FROM THIS COURT'S TEACHINGS AND PREVIOUSLY SETTLED LAW BY CONFLATING "COMMERCIAL SUCCESS" AND "FAILURE OF OTHERS" AS INDICATORS OF NONOBVIOUSNESS

A claimed invention is not patentable if it "would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103. In the leading case on nonobviousness, *Graham* v. *John Deere Co.*, 383 U.S. 1, 17 (1966), this Court specifically listed an invention's "commercial success" and the "failure of others" to

have solved the same problem as distinct considerations bearing on the obviousness inquiry. In contrast, the decision below erases any distinction. Pet. App. 23a-24a. The Court should not permit that result.

The requirement of nonobviousness traces back to this Court's decision in *Hotchkiss* v. *Greenwood*, 52 U.S. (11 How.) 248 (1851), but it was not codified until 1952. *See Graham*, 383 U.S. at 11-12, 15. In 1966, the Court concluded that the statutory provision "was intended merely as a codification of judicial precedents embracing the *Hotchkiss* condition." *Id.* at 17. The Court then described four "basic factual inquiries" that underlie analysis of nonobviousness:

(1) "the scope and content of the prior art";

(2) "differences between the prior art and the claims at issue";

(3) "the level of ordinary skill in the pertinent art"; and

(4) "[s]uch secondary considerations as *commercial success*, long felt but unsolved needs, *failure of others*, etc."

Id. at 17-18 (emphasis added).[3]

Before this case, the Federal Circuit followed *Graham*, treating commercial success and "failure of others" as separate secondary indicators of nonobviousness. *See, e.g.*, *Brown & Williamson Tobacco Corp.* v. *Philip Morris Inc.*, 229 F.3d 1120, 1129-1130 (Fed. Cir. 2000); *Ecolochem, Inc.* v. *Southern Cal. Edison Co.*, 227 F.3d 1361, 1376-1378, 1380 (Fed. Cir. 2000). In this case, however, the court took a sharp turn, holding that the "rationale" for considering

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[3] In the companion case of *United States* v. *Adams*, 383 U.S. 39, 51-52 (1966), the Court cited multiple "secondary considerations" supporting nonobviousness. In two later decisions, the Court has clarified that "secondary considerations" such as commercial success do not supplant the basic inquiry into whether there was an "invention." *Sakraida* v. *Ag Pro, Inc.*, 425 U.S. 273, 278-279, 282-283 (1976); *Anderson's-Black Rock, Inc.* v. *Pavement Salvage Co.*, 396 U.S. 57, 61 (1969).

commercial success "has no force" unless the success supports an inference of "failure of others." Pet. App. 23a-24a.

That holding conflicts with this Court's consistent recognition that commercial success *intrinsically* supports patentability. In *Smith* v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876), the Court reasoned that success could help "justify the inference" that an innovation involved more than a mere design choice or "substitution of one material for another" and "was, in truth, invention." Later cases repeatedly relied on commercial success as evidence of patentability without requiring that it be evidence of "failure of others." *E.g.*, *Hobbs* v. *Beach*, 180 U.S. 383, 393 (1901); *Topliff* v. *Topliff*, 145 U.S. 156, 164 (1892); *Washburn & Moen Mfg. Co.* v. *Beat 'Em All Barbed-Wire Co.*, 143 U.S. 275, 284, 292 (1892); *Magowan* v. *New York Belting & Packing Co.*, 141 U.S. 332, 343 (1891); *Consolidated Safety-Valve Co.* v. *Crosby Steam Gage & Value Co.*, 113 U.S. 157, 179 (1885). To the contrary, the Court recognized that commercial success, "*of itself*, is persuasive evidence of ... invention." *Minerals Separation, Ltd.* v. *James M. Hyde*, 242 U.S. 261, 270 (1916) (emphasis added); *see also Keystone Mfg. Co.* v. *Adams*, 151 U.S. 139, 143-144 (1894) ("fact that a device has gone into general use, and has displaced other devices ...," "is always of importance, and is entitled to weight, when the question is whether the machine exhibits patentable invention"); *cf. Goodyear Tire & Rubber Co.* v. *Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944). *Graham* acknowledged and preserved this line of precedent by listing "commercial success" as the first of the three "secondary considerations" that it expressly mentioned as part of the obviousness analysis. 383 U.S. at 17-18; *see also id.* at 35-36 (citing *Reiner* v. *I. Leon Co.*, 285 F.2d 501, 504 (2d Cir. 1960) (L. Hand, J.)).

Following *Graham*, courts of appeals repeatedly recognized the probative value of commercial success without tying it to "failure of others." *E.g.*, *Sarkisian* v. *Winn-Proof Corp.*, 697 F.2d 1313, 1320 (9th Cir. 1983); *Black & Decker Mfg. Co.* v. *Sears, Roebuck & Co.*, 679 F.2d 1101, 1104 (4th Cir. 1982); *Illinois Tool Works, Inc.* v. *Sweetheart Plastics,*

Inc., 436 F.2d 1180, 1187 (7th Cir. 1971). After the Federal Circuit was created in 1982, it too recognized commercial success as an independent factor supporting nonobviousness—even when there was "no evidence" of failure of others. *Brown & Williamson*, 229 F.3d at 1130-1131 ("district court erred by not considering the success" of a product, despite findings of "no evidence" of failure of others, "no long-felt but unmet need," and "no unexpected results"); *Ecolochem*, 227 F.3d at 1378, 1380 (affirming findings of "no long-felt but unsolved need" and "no failure by others," but holding that "district court clearly erred" in failing to credit evidence of "commercial success"); *see also* Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. Rev. 1, 9 (1989) ("[T]he CAFC now requires evidence concerning the commercial success of patented invention, on the theory that the willingness of others to buy it demonstrates the extent to which it contributes to the field.").

That traditional approach makes perfect sense. It is not true that commercial success suggests nonobviousness only to the extent it provides "a basis for inferring that [other] attempts [to solve a problem] have been made and have failed." Pet. App. 23a (internal quotation marks omitted). For example, courts have recognized that third-party praise of an innovation can independently suggest that the invention involved was not obvious. *Ecolochem*, 227 F.3d at 1380; *see also Vulcan Eng'g Co.* v. *Fata Aluminum, Inc.*, 278 F.3d 1366, 1373 (Fed. Cir. 2002). Commercial success can be viewed as a particularly meaningful form of praise by the "interested public." *Arkie Lures, Inc.* v. *Gene Larew Tackle, Inc.*, 119 F.3d 953, 957-958 (Fed. Cir. 1997); *see also Illinois Tool Works*, 436 F.2d at 1187 ("We do not believe that the tribute of the trade and the marketplace can be ignored when it is so overwhelming in scope and magnitude."). This is especially true where the invention has a "specialized market" of "experts"—such as the physicians who prescribed weekly-dose Fosamax® in dramatically increased numbers. Spencer H. Boyer, *Commercial Success as Evidence of Patentability*, 37 Fordham L. Rev. 573, 594 (1969).

Commercial success also supports an inference of nonobviousness by providing objective, non-technical proof of significant, real-world differences between the claimed invention and prior products. *See Gillette Co.* v. *S.C. Johnson & Son, Inc.*, 919 F.2d 720, 725 (Fed. Cir. 1990). In the pharmaceutical arts, the discovery of unexpected properties is frequently the basis for awarding a patent for a specific compound, even where the larger chemical genus that includes the compound was disclosed by (or obvious in light of) the prior art. *See In re Papesch*, 315 F.2d 381, 386-391 (C.C.P.A. 1963) (discussing cases); *see also In re Soni*, 54 F.3d 746, 749-751 (Fed. Cir. 1995). The commercial success of a claimed compound can corroborate more technical evidence of such unexpected properties by showing that a knowledgeable and unbiased marketplace recognized the claimed invention as a substantial advance over what was available before. *See, e.g., Ortho-McNeil Pharm., Inc.* v. *Mylan Labs., Inc.*, 348 F. Supp. 2d 713, 755-757, 760-761 (N.D. W. Va. 2004); *cf. Sarkisian*, 697 F.2d at 1320-1321 (commercial success "support[ed court's] determination that [portable-stand] device produced results that were unusual or surprising").

Similarly, courts have recognized that commercial success is evidence "that the patent under attack served to satisfy a long felt want." *Lorenz* v. *F.W. Woolworth Co.*, 305 F.2d 102, 104-105 (2d Cir. 1962) (internal quotation marks omitted); *see also Greening Nursery Co.* v. *J&R Tool Mfg. Co.*, 376 F.2d 738, 742 (8th Cir. 1967). Long-felt need can, in turn, support nonobviousness even without an inference of "failure of others." Long-felt need can corroborate a claim that an invention solved a real-world problem and thus represented more than a design choice. Further, the long-established existence of this demand can show that even the holder of a patent in an underlying invention, such as Merck, had an incentive to develop a desired improvement substantially earlier. *Cf.* Richard L. Robbins, Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. Pa. L. Rev. 1169, 1172 (1964) ("[e]xistence of [a] defect creates a demand for its correction, and it is reasonable to infer that the defect would not persist were the

solution 'obvious'"), *cited in Graham*, 383 U.S. at 36, *and in the opinion below*, Pet. App. 23a. The original patent holder's failure to do so, like "failure of others," supports a conclusion of nonobviousness.

In sum, the Federal Circuit's treatment of commercial success in this case defies this Court's decisions, other long-standing precedent, and the logic underlying both. As this Court has recognized, commercial success is a powerful *general* indicator that an inventor has contributed something new and patent-worthy to the art. The objective approval of the marketplace is strong evidence of genuine innovation. *Safety Car Heating & Lighting Co.* v. *General Elec. Co.*, 155 F.2d 937, 939 (2d Cir. 1946) (L. Hand, J.) ("the extent to which [an invention] superseded what had gone before" is "perhaps most important" among factors in "apprais[ing] the originality involved"). It should weigh heavily in favor of patentability regardless of whether there is additional evidence of a competitive market in the "race to invent."

II. Precluding Consideration Of Commercial Success Because Of Prior Exclusive Rights Improperly Truncates The Obviousness Inquiry And Reduces Incentives For Innovation

Even if commercial success were relevant only to support an inference of failure of others, the Federal Circuit would still have erred in reasoning that such failure cannot be inferred where the inventor of an improvement also had other rights under U.S. patent and drug laws that might have restricted third-party activity (Pet. App. 23a-24a).

The Federal Circuit's per se rule against such an inference is not grounded in evidence or in market reality. First, the inventors who develop an improvement may (as here) be employees of an entity that holds pre-existing rights, while the "others" who fail to develop the improvement may be other employees, affiliates, or licensees of the same entity. In this very case, when Merck in the mid-1990s sponsored research on the gastrointestinal side effects of alendronate, that research, if anything, taught away from the weekly dos-

ing schedule later developed by Merck inventors. Pet. App. 87a-88a.

Second, the existence of exclusive rights under U.S. patent and drug laws does not prevent others from pursuing improvements, even in the United States. For example, despite Merck's allegedly preclusive rights (Pet. App. 24a), one of respondent's affiliates, Teva Pharmaceutical Industries, Ltd., has patented an improvement involving "a dosage form suitable for delivering a therapeutic bisphosphonate *such as alendronate*." U.S. Patent No. 6,476,006, abstract (issued Nov. 5, 2002) (emphasis added). Indeed, "blocking" patents—*i.e.*, patents under which each holder may prevent the other from exploiting its own invention in the most effective way—frequently result when a later inventor patents an improvement on an earlier invention. *See Amgen, Inc.* v. *Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 287 & r.104 (D. Mass. 2004) (in biotechnology, "blocking patents are common"); *see also Prima Tek II, L.L.C.* v. *A-Roo Co.*, 222 F.3d 1372, 1379 n.2 (Fed. Cir. 2000) (describing an "often occur[ring]" blocking-patent situation); *cf. Cochrane* v. *Deener*, 94 U.S. 780, 787 (1876) ("One invention may include within it many others, and each and all may be valid at the same time."). These realities refute the panel's unsupported assertion that pre-existing rights prevent innovation by others.

That is not surprising. The exclusive rights the Federal Circuit discusses do not preclude experimentation or commercial exploitation by others. Even when a senior party has such rights, other parties may still develop and exploit improvements by, for example, (1) patenting the idea for an improvement, (2) obtaining a license with respect to the pre-existing rights, (3) developing and exploiting an improvement abroad, or (4) pre-commercialization development and testing "reasonably related to the development and submission of information" under certain federal laws, 35 U.S.C. § 271(e)(1); *see also Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2380 (2005). The possibility of exploitation abroad is particularly easy to understand and impossible

to deny. PhRMA's members spent an estimated $8.2 billion on foreign research and development in 2004 alone, PhRMA, *Pharmaceutical Industry Profile 2005—From Laboratory to Patient: Pathways to Biopharmaceutical Innovation* 2 fig. 1.1, *available at* http://www.phrma.org/publications/publications//2005-03-17.1143.pdf, and respondent Teva Pharmaceuticals USA is itself a U.S. subsidiary of a foreign corporation.

In addition to being groundless, the Federal Circuit's per se rule is unfair. It discriminates against innovators who bring their inventions to the Patent Office and the market at an early stage—thus disclosing them to the public, as patent law encourages, *see Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-151 (1989)—and who later improve their original inventions. Under the Federal Circuit's new rule, such innovators will typically find themselves barred from using commercial success either to establish an improvement's patentability before the PTO or to defend an improvement patent in later litigation. This bar on citing commercial success in the securing or defense of improvement rights lessens the value of patent rights all along the chain, by making the original rights a less desirable basis for further innovation and by making the improvement rights both less attainable and, if attained, less secure. The Federal Circuit's rule thus decreases the incentive offered by the patent system both for initial inventions and for improvements by the holder of the original rights.

The situation is different for third-party improvers. They will likely be able to rely on commercial success to confirm the validity of *their* follow-on patents because, even according to the Federal Circuit's logic, there will have been at least one "other"—the holder of the rights to the original invention—who could have developed the improvement but did not. Hence, an improvement patent will be both easier to obtain and more secure against challenge, and thus more valuable, when it is developed by a third-party improver.

That result is inconsistent with the goals of patent law. The law should encourage improvements to existing inven-

tions without regard to who makes them. "A level playing ground for the marketplace of ideas" is the surest means to serve the constitutional purpose of "promot[ing] the Progress of . . . useful Arts," U.S. Const. art. I, § 8, cl. 8. *Panduit Corp.* v. *Denniston Mfg. Co.*, 810 F.2d 1561, 1573-1574 (Fed. Cir. 1987). By reducing the reward offered for improvements by the holder of the original patent—who will often be positioned to develop them most quickly and at lowest cost—the Federal Circuit's rule plays favorites to the detriment of the public.

III. The Decision Below Will Affect A Wide Range Of Cases And Transform Commercial Success Into An Issue Requiring A Complex Threshold Inquiry

The Federal Circuit has already made clear that its new approach to commercial success reaches far beyond this case. In *Syntex (U.S.A.) LLC* v. *Apotex, Inc.*, 407 F.3d 1371, 1379, 1383 (Fed. Cir. 2005), the court vacated a holding of nonobviousness and directed that, on remand, "the district court should consider the impact of the *Merck* analysis." Whenever "the active ingredient in [a patented] formulation was previously patented," the court instructed, "the trial court should carefully consider whether the nexus requirement of our law is satisfied." *Id.* Moreover, because "the *Merck* analysis" makes no distinction on technological grounds, its effects will not be confined to pharmaceutical inventions but will extend to improvement patents in all areas.

Those effects warrant review by this Court. Like technological progress in general, pharmaceutical innovation is frequently cumulative and incremental. Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations*, in 14 *Investing in Health: The Social and Economic Benefits of Health Care Innovation* 77, 78 (I. Farquhar et al. eds., 2001). Of the 996 new drug applications approved by the Food and Drug Administration from 1994 through 2004, 597 were for improvements to, or new uses for or variations of, existing drugs or administra-

tion regimens.[4] The value of such improvements is significant. By reducing side effects (as in this case), improving effectiveness, or enabling a choice among therapies that can be tailored for individual patients, diseases, or symptoms, a diverse array of related drugs and treatment formulations can significantly improve both medical results and patients' quality of life. *Id.* at 78-79.

Despite their importance, such improvements necessarily have strong ties to pre-existing art and are therefore especially vulnerable to allegations of obviousness made in hindsight. Like other "secondary considerations," commercial success is meant to help courts guard against such hindsight bias and "resist the temptation to read into the prior art the teachings of the invention in issue." *Graham*, 383 U.S. at 36. Yet the Federal Circuit has now selectively eliminated that protection for the entity perhaps most likely to pursue an improvement—the original patent holder. That departure from this Court's teaching threatens to slow the rate of innovation in the pharmaceutical industry. *Cf.* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 3, p. 11 & n.48 (2003) (reporting estimate that, without patent protection, pharmaceutical "innovation would decrease by approximately 60%"), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf; Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in *Science and Cents: Exploring the Economics of Biotechnology* 87, 88 (J. Duca & M. Yücel eds. 2003) (discussing "[t]he importance of patents to pharmaceutical innovation"), *available at* http://www.dallasfed.org/research/pubs/science/index.html.

In a wide array of cases, the Federal Circuit's reformulation will also complicate patent litigation—and thereby add to the cost of defending and enforcing patent rights—in a

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[4] Food and Drug Administration, *CDER NDAs Approved in Calendar Years 1990-2004 by Therapeutic Potential and Chemical Type* (Mar. 22, 2005), *available at* http://www.fda.gov/cder/rdmt/pstable.htm.

way that undermines the basic purpose of the commercial success inquiry. *Graham*'s "secondary considerations" of nonobviousness are meant to provide relatively simple, non-technical, objective evidence of nonobviousness, as judged by a marketplace whose opinions are not litigation-driven. They are useful because they "focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation." 383 U.S. at 35-36; *cf. Arkie Lures, Inc.* v. *Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997).

Accordingly, until now the rule was that once a patent holder provided evidence of a "nexus between commercial success and the patented invention," it became the challenger's "burden to show that [such evidence] should not be given weight." *Winner Int'l Royalty Corp.* v. *Wang*, 202 F.3d 1340, 1350-1351 (Fed. Cir. 2000) (internal quotation marks omitted). "A prima facie case of nexus [was] generally made out when the patentee show[ed] both that there [was] commercial success, and that the thing (product or method) that [was] commercially successful [was] the invention disclosed and claimed in the patent." *Demaco Corp.* v. *F. von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). Requiring further threshold proof that commercial success was "*not* due to factors other than the patented invention" was viewed as "unfairly burdensome, and contrary to the ordinary rules of evidence." *Id.* at 1394 (emphasis in original).

The decision below upsets the established balance of burdens between patent defender and challenger. As part of the threshold inquiry into commercial success, the patent holder will now have to show (1) that commercial success has a further "nexus" with the "failure of others" to invent the improvement, and (2) that the patent holder lacked pre-existing exclusive U.S. rights to the improved invention. In *Syntex*, the Federal Circuit confirmed that these requirements are, like the previous requirement of a causal "nexus," *threshold* burdens that a patent holder must carry to estab-

lish the very relevance of commercial success. 407 F.3d at 1383 ("the trial court should carefully consider whether the *nexus requirement* of our law is satisfied" (emphasis added)). Thus, a patent holder invoking commercial success must now show at the threshold not only that the success was attributable to the invention, but also that there was a competitive market to develop the invention in the first instance.

Proof that such a market existed will often require just the sort of litigation over "technical issues" that reference to "secondary considerations" is meant to avoid. *Graham*, 383 U.S. at 35-36. In almost any situation, there will be both patent and non-patent barriers to market entry that patent challengers will be able to argue break the inferential link between commercial success and the failure of others. Parties can now routinely expect to litigate whether past market conditions permitted competition in innovation. The Federal Circuit has thus added to the already high cost of enforcing patent rights by transforming commercial success into a complex inquiry from the start. Yet "secondary considerations" are intended not to complicate analysis, but to allow straightforward, objective evidence to act as a real-world check on a court's analysis of otherwise technical issues. *Id.*; *see also Reiner*, 285 F.2d at 504, *cited in Graham*, 383 U.S. at 36; Robbins, *supra*, at 1171-1172.

For these reasons, the decision below transforms the commercial success inquiry in ways that are inconsistent not only with its logic, but with its basic purposes as identified by this Court. This transformation will affect not only cases involving pharmaceuticals, but improvement cases in all fields of invention. The decision accordingly warrants this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

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MERCK & CO., INC.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

Teva's brief in opposition defends very little of what a divided panel actually said in reversing the district court and invalidating one of the most important patents in the pharmaceutical field. Rather, Teva's brief advances numerous factual contentions that the finder of fact did *not* accept, and legal contentions that are *not* the ones the Federal Circuit gave as its bases for reversing. Such a document – akin to first-instance proposed findings of fact and conclusions of law in a trial court – only underscores that the gravamen of Teva's case is issues it lost in the *trial* court, and that no sustainable basis for reversal on appeal existed. To reverse nevertheless, the Federal Circuit acted as if it were the original factfinder and adopted a new rule of law on commercial success, producing several dissents.

Teva does not dispute the continuing disagreement within the Federal Circuit, refute the disarray caused by that court's *de novo* approach to reviewing district court claim construction decisions, or even defend that approach. The Federal Circuit's insupportable methodology has become entrenched by three successive en banc cases[1] declaring and reaffirming that claim construction involves no underlying factual issues to which the "clearly erroneous" standard of Rule 52(a) attaches – a fundamentally mistaken position that warrants review by this Court.

Similarly, Teva does not defend the Federal Circuit's trampling of Rule 52(a) en route to declaring Merck's '329 patent invalid for obviousness under 35 U.S.C. § 103(a). Instead, Teva falsely presumes that the "same invention" was in the prior art – when in fact the prior art contained *no invention at all*. Thus, Teva avoids confronting the Federal Circuit's disregard of the district court's factual determinations concerning this Court's "*Graham* factors" and the secondary considerations required in

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[1] See *Phillips* v. *AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc); *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc); *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 897 (Fed. Cir. 1995) (en banc), aff'd in part, 517 U.S. 370 (1996).

evaluating obviousness. Indeed, Teva recasts the Federal Circuit's invalidity rationale as rejecting a "legal" theory (Opp. 15) rather than defending its impermissible reweighing of the district court's detailed findings, even though the Federal Circuit summarily declared blanket "clear error" in every finding contrary to its desired invalidity outcome. Pet. App. 22a; see also Pet. App. 16a ("As explained below, we find clear error in the trial court's findings on these underlying facts.").

Finally, in defending the Federal Circuit's declaration that Merck's strong evidence of "commercial success" and "nexus" to the claimed invention was entitled to "no force," Teva ignores that the Federal Circuit again impermissibly reweighed this evidence *and* announced a new rule of law making a long-standing category of evidence irrelevant.

I. No Issue in this Case Is "Moot"

Teva tries to sidestep Merck's first question by alleging that the parties' vigorous dispute about claim construction is "moot." Opp. 8. Teva points to nothing outside of this litigation that has created any arguable source for the alleged mootness. Instead, Teva's "mootness" theory arises solely from the footnote in which the Federal Circuit's majority declared that "[i]t makes no difference to this conclusion [of invalidity] whether the court begins with the claim construction set forth by the panel or by the dissent." App. 16a n.10. Based on nothing more, Teva argues that correcting the Federal Circuit's flawed *de novo* methodology and erroneous construction in this case would not affect the outcome. Opp. 9. That is simply wrong.

As explained at Pet. 23 n.14, the Federal Circuit's footnoted attempt to insulate its claim construction approach and result from further scrutiny is belied by its own detailed claim construction analysis and its concession that its invalidity holding was reached "[i]n light of the corrected claim construction." Pet. App. 15a. At no prior point did Teva accept Merck's vastly different claim construction or contend that the parties' lengthy and hotly contested claim construction dispute was irrelevant. Even now, Teva tries to bolster the Federal Circuit's acceptance

of the claim construction rejected by District Judge Farnan. Opp. 9-13.

In this case, as in any other patent case, a complete and proper claim construction is a necessary prerequisite to and thus inextricably intertwined with any subsequent invalidity analysis. An exception to that rule cannot be created by a Federal Circuit footnote that really does nothing more than expose that court's result-oriented invalidity approach. In *Cardinal Chem. Co.* v. *Morton Int'l*, 508 U.S. 83 (1993), this Court halted the Federal Circuit's practice of vacating district courts' invalidity holdings (in cases with declaratory judgment counterclaims) on the ground that all invalidity issues were rendered "moot" once the Federal Circuit affirmed a finding of no infringement. Similarly, a declaration of the type in the Federal Circuit's footnote cannot moot this Court's ability to review the Federal Circuit's *de novo* claim construction.

Notwithstanding footnote 10, the Federal Circuit majority proved that it thought the parties' dispute about claim construction *did* matter to the outcome by resolving that dispute in a lengthy discussion, which the court presumably did not intend to constitute a mere advisory opinion. The court even described its reversal on obviousness as being reached "[i]n light of the corrected claim construction." Pet. App. 15a. Judge Rader's panel dissent focused *entirely* on claim construction, reflecting his view that claim construction had "consequences" (Pet. App. 26a) in this "very close case" (*id.* at 33a) in which the district court's "diligent and intelligent process *and resolution* earned more respect than it received" (*id.* (emphasis added)).[2]

Teva asserts that "the difference between exactly 70 mg * * * and 80 mg, specified by the *Lunar News*, is not a distinc-

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[2] It is fanciful to suggest (Opp. 7) that Judge Rader did not urge a different outcome for this case. Judge Rader's repeated references to the closeness of this case, his express citation of the district court's *resolution* of the case, and the very labeling of his opinion as a dissent rather than a concurrence in the judgment all confirm that he would have affirmed rather than reversed the district court.

tion that could make Merck's invention unobvious." Opp. 9. It is, however, no mere coincidence that the district court rejected both Teva's claim construction and its obviousness defense, whereas the Federal Circuit accepted both. The district court correctly understood that such a dosing difference can be significant within the art, and found that Teva's evidence at trial failed to prove the equivalence of the two doses. "[A]lthough Dr. Russell testified that 80 mg and 70 mg are the same for all practical purposes, * * * in rendering his opinion Dr. Russell did not take into account this Court's construction * * *. Dr. Russell provided no evidence to support his conclusion that 70 and 80 mg were equivalent." Pet. App. 72a. Not only were the validity findings tied to the claim construction, but the *finder of fact* was not persuaded that the difference between 80- and 70-mg doses is insignificant based on the evidence at trial. Teva and the Federal Circuit have no legal basis for insisting on such a finding.

II. This Court Should Review and Reject the Federal Circuit's Refusal to Give Deferential Review to Factual Findings Underlying Claim Construction

Other than its incorrect "mootness" contention, Teva offers nothing to rebut Merck's showing why resolution by this Court of the correct manner of appellate review applicable to district court claim constructions rulings is critically important. Indeed, Teva's conspicuous refusal to cite, much less defend, the Federal Circuit's en banc decisions in *Markman*, *Cybor*, and *Phillips* confirms the need for this Court to review and correct that clearly flawed appellate methodology. See Pet. 18-19 & n.8.

Teva's efforts to defend the merits of the Federal Circuit's *de novo* claim construction are misplaced and mistaken. First, as Judge Rader pointed out, "[t]his is the classic 'close case,' so close in fact that ultimately two federal judges (one of whom conducted an entire bench trial on this issue) and the United States Patent and Trademark Office agreed with [Merck] and two federal judges agreed with [Teva]." Pet. App. 32a. This is exactly the kind of case where there could be no clear error in

the underlying findings. *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985). Hence, if this Court decides that claim construction does involve resolving underlying issues of fact, it would be immaterial whether this Court or the Federal Circuit agrees with Merck or with Teva. *Id.* at 573-574. Resolution of the question posed would be determinative of the disputed claim phrase here – the district court's admittedly reasonable construction would have to be accepted, even if an appellate court conceived a construction it thought "more reasonable." Pet. App. 13a.

As the district court understood, the '329 patent contains an explicit definition for the entire claim phrase that was truly at issue. Claim 23, the only claim addressed in Teva's opposition, recites "[a] method for treating osteoporosis * * * comprising administering *about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis*." Pet. 3. The definition explicitly states that "the phrase 'about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronate acid active weight basis' *means* that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid." Pet. 7 (quoting C.A. App. 3594-95) (emphasis altered). Thus, the specification defines the entire phrase within quotes, not just for the word "about" and not just for the phrase "about 70 mg" that appear within the overall defined phrase.

Neither Teva nor the Federal Circuit has made any attempt to be faithful to what the patent says the disputed phrase "means." The Federal Circuit resorted to declaring its "belie[f]" that the patent's definitional clarity was "likely an inadvertent error," Pet. App. 13a n.8, an exercise of appellate factfinding so bizarre that Teva says not one word in defense of it. Yet Teva resorts to what may be an even more bizarre tactic, simply omitting the word "means" from its quotation of the patent's definition – despite emphasizing that the key question is whether the specification says in so many words what the key phrase "*means*." See Opp. 10. Such gymnastics to avoid the patent's

clear definition both show the error of the decision below and confirm that the standard of review mattered greatly in this case.

In any event, resolution of any ambiguity in the claim language requires a trial court to evaluate the conflicting evidence cited by both parties bearing on the ambiguous word or phrase. Merck's citation to certain portions of the specification and Teva's citation to others does not change the fundamental nature of the pertinent inquiry – a resolution of conflicting evidence, which is factfinding, even when done by a trial court on a matter reserved for its (rather than a jury's) decision. Thus, as amicus BPLA observes, "this case * * * provides an excellent opportunity to reconsider the Federal Circuit's *de novo* review standard." BPLA Amicus Br. 4.

Second, Teva's defense of the Federal Circuit's claim construction misdirects this Court by addressing a claim phrase that was never at issue. Contrary to Teva's position, no one at trial disputed the ordinary meaning of the term "about" and no court should have decided whether Merck's specification clearly redefined the claim phrase "about 70 mg" to mean "exactly 70 mg." Opp. 9. Even if the meaning of the term "about" or "about 70 mg" were both at issue and ambiguous, resolving their meaning would similarly be a question of fact to be determined by weighing the conflicting evidence related to those terms.[3]

Finally, Teva complains that Merck would require the Federal Circuit always to defer to a district court's construction even if it was contrary to the entire patent. Opp. 12. That is untrue. First, if all the evidence supports only one reasonable interpretation, there is no ambiguity, and no factfinder should find otherwise. In that case, a district court's contrary construction

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[3] Where expert or inventor testimony is offered, credibility determinations may also factor into a trial court's fact finding. See Pet. 8. No Merck witness testified on the meaning of "about 70 mg" because that phrase was not at issue. Opp. 12. While Teva concedes that the district court did not credit Teva's expert on that phrase, Teva ignores that the district court recognized that Dr. Russell understood the specification's express definition for the entire claim phrase at issue. Pet. 8.

can and should be reversed, as would any other factfinding on which the evidence permits no reasonable dispute. See *Warner Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 517 U.S. 17, 39 n.8 (1997). Here, however, Teva merely recites its version of the disputed evidence in disregard of Merck's directly contrary evidence credited by the finder of fact (Pet. App. 58a-64a). This highlights rather than disproves the existence of underlying factual disputes that were plausibly resolved at trial.

Teva's opposition also confirms that the Federal Circuit's form of *de novo* review wrongly encourages patent litigants to proceed on appeal as if they have free license to reargue the factual issues underlying their claim construction positions from scratch. This Court should not allow the Federal Circuit to ignore Rule 52(a) any longer. Moreover, there can be no question that the Federal Circuit's *de novo* methodology that refuses to accord Rule 52(a) deference to district court fact findings has spawned widespread and unacceptable confusion, unpredictability, and uncertainty in patent cases for more than a decade. See Pet. 18-19; BPLA Amicus Br. 9-11. The time has come for this Court to review that entrenched but controversial Federal Circuit practice, and this "classic 'close case'" (Pet. App. 32a) is the perfect vehicle in which to do so.

III. This Court Should Correct the Federal Circuit's Insistence that Any Factual Finding that Got in the Way of the Majority's Obviousness Conclusion Was Automatically "Clearly Erroneous"

With obviousness, as with claim construction, Teva refuses to address or refute the substance of Merck's challenge to the Federal Circuit's increasingly bold disregard of the limits on its appellate review authority under Fed. R. Civ. P. 52(a). Contrary to Teva's assertion (Opp. 13), Merck is not seeking to alter an appellate court's role as specified by this Court in *Bessemer City*, but is urging this Court to rein the Federal Circuit back into operating within those important limits. Hence, Teva has left wholly unrebutted Merck's showing that the Federal Circuit's approach to *de novo* review of claim construction has equally infected its approach when reviewing other legal issues

such as obviousness that indisputably have underlying factfindings. See Pet. 23-24.

Teva's opposition argues invalidity on the ground – *not* accepted by the Federal Circuit – that the "same invention" was allegedly in the prior art, rather than confronting the district court's explicit and detailed findings (Pet. App. 83a-94a) showing why the differences between Merck's invention and the prior art as a whole were nonobvious. Even the Federal Circuit agreed that the *Lunar News* articles did not disclose the "same invention" as the '329 patent and thus could not anticipate under 35 U.S.C. § 102. Pet. App. 16a. Indeed, the *Lunar News* articles on which Teva and the Federal Circuit exclusively rely do not disclose an invention, but merely contain an untested suggestion and a hope for future improvements.

The two *Lunar News* articles merely state that alendronate "*potentially could be* given in a 40 or 80 mg dose once/week" or that "[a]n intermittent treatment program (for example, once per week * * *) * * * *needs to be tested*." C.A. App. 3677, 3641 (emphasis added). Teva's Wright Brothers analogy (Opp. 16 n.4) usefully illustrates the point: Teva's premise that the *Lunar News* suggestions constitute an earlier invention of the '329 patent would mean that the Wright Brothers' patents would have been invalidated by countless articles in the pre-1900s predicting that man one day potentially could build bird-like flying machines and suggesting that such ideas need to be tested.

The critical question for this Court's review is whether to condone the Federal Circuit's cavalier practice of reaching its own legal conclusion before announcing its disregard or reversal of any contrary district court finding. The issue is not whether this Court would agree in the first instance with Merck and the district court or with Teva and the Federal Circuit on whether Merck's invention was obvious. Rather than trying to defend the Federal Circuit's inverted approach, Teva advances the preposterous propositions that the Federal Circuit merely rejected "Merck's legal theory" (Opp. 15) and "did not base its decision on a rejection of district court fact findings." Opp. 16. It is telling that Teva mischaracterizes the Federal Circuit's stated

basis for its obviousness conclusion rather than attempting to justify the court's *de novo* review methodology.

Contrary to Teva's premise, Merck's nonobviousness proof did not require "nullifying" the Lunar News articles as prior art, nor did Merck's position require the district court to find that Dr. Mazess was not an expert. Opp. 6, 15-16. Instead, Merck rebutted Teva's evidence with extensive evidence showing that Dr. Mazess's untested conjecture would not have persuaded those skilled in the art of treating osteoporosis patients at the pertinent time that alendronate could be safely administered at doses higher than 20 mg. See Pet. 9-10. Regardless of his credentials, the district court properly weighed all the conflicting evidence, including the other prior art and expert testimony, and found that Dr. Mazess's naked suggestions provided no advance to the art and could not overcome the prior art teachings as a whole. See Pet. 25-27. Thus, it is the Federal Circuit's *sua sponte* findings on appeal that are unsupported. Its invalidity conclusion is the product of improper reweighing of disputed evidence and result-oriented hindsight, a continuing problem in that court worthy of this Court's review.

IV. As the Amicus Briefs Attest, the Federal Circuit's Refusal to Give Weight to the Commercial Success of an Improvement Patent Merits Review

Merck offers two main points regarding Teva's lengthy but mostly irrelevant defense of the Federal Circuit's misguided new rule disabling the probative value of commercial success evidence in cases where a patentee improves its own patented invention. Pet. App. 23a-24a. First, the most Teva can assert now is that the commercial success of Merck's once-weekly Fosamax® product "is not necessarily attributable to its non-obviousness." Opp. 18. On its face, a proposition that is "not necessarily" true is the epitome of a disputed factual question, which the district court resolved in favor of Merck. Pet. App. 91a-93a. The Federal Circuit's and Teva's preference that the district court have given Merck's evidence less weight is not a proper basis for inventing on appeal a new rule of law that throws that evidence out altogether.

Second, the Federal Circuit's new rule creating a broad and virtually irrebuttable presumption discriminating against patent owners that have prior market exclusivity is ill conceived, unfounded, and contrary to the fundamental premise of the patent system to encourage innovations over current technology. Pet. 28-29; PhRMA Amicus Br.; Procter & Gamble Amicus Br. Notably, Teva does not acknowledge or explain its own efforts to develop alendronate-based osteoporosis treatment inventions, despite Merck's existing exclusivities. See Pet. 29. Teva also offers no justification for creating this obstacle to obtaining improvement patents. See Pet. 28-29. If improvement patents are encouraged only at spaced intervals of 20 years, the constitutional goal of promoting progress of science and useful arts will certainly be thwarted.

As further detailed in the PhRMA amicus brief, the Federal Circuit's assumption that no one else has incentive to innovate in the face of existing patent or other market exclusivity is simply wrong. See PhRMA Br. 11-13 (listing incentives from obtaining separate patent rights, licensing or cross-licensing opportunities, foreign sales and licensing, and further research incentives). On that basis alone, the rule should be reviewed and reversed by this Court. Taken as a whole, the defective factual assumptions underlying the Federal Circuit's new rule confirm why such rulemaking is better done by Congress, not the courts.

CONCLUSION

For the reasons stated above and in the petition, Merck's petition for a writ of certiorari should be granted.

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BRIEF OF THE BOSTON PATENT LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF MERCK & CO.'S PETITION FOR CERTIORARI

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INTEREST OF *AMICUS CURIAE*

The Boston Patent Law Association ("BPLA") is an association of intellectual property professionals providing programs and forums for the exchange of ideas and information about patent and other intellectual property rights. The BPLA is neutral as between the litigants, Merck & Co. and Teva Pharmaceuticals USA, Inc.. But the BPLA is concerned how *de novo* review of claim construction affects patent litigation and the patent system generally. This case highlights the shortcomings of *de novo* review.[1]

SUMMARY OF ARGUMENT

The elephant in the room, which all patent professionals recognize but, in the wake of *Markman v. Westview Instruments*, hesitate to say aloud, is that claim construction involves factual inquiry. While a patent is certainly a legal document, it is also a technical document meant to be read and understood by artisans in the field of invention.

Thus, the standard for interpreting a patent is not how any reasonable person would read the document but rather how "one of ordinary skill in the art" would. Indeed, patents contain jargon that, while foreign to most of us, is readily understood by an inventor's fellow engineers, scientists, or mechanics. Judges thus rely on technical experts to inform them how an artisan would view the patented technology. In doing so, judges find facts and weigh credibility.

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[1] Pursuant to Supreme Court Rule 37.6, no party or its counsel authored any part of this brief. No person or entity, other than the BPLA and its counsel, Bromberg & Sunstein LLP, contributed money for the preparation or submission of this brief. The parties have consented to the filing of this *amicus* brief. The consent letters have been lodged with the Court.

Claim construction, however, has lost its focus on the technology and has instead devolved into a war of semantics. Terms such as "on" or "or" or, as in this case, "about," control patent scope rather than the technology that the inventor invented. That cannot be the original intent of the Constitution, which was to preserve to inventors their inventions, not to tangle them up in words.

De novo review biases the Federal Circuit away from expert testimony that informs a trial judge's determination of how skilled artisans would have understood the patented invention. Instead, the Federal Circuit tends to substitute its own (lay) reading of the patent for that of the skilled artisan. As a result, claim construction has become less about the technology and more about semantics.

Moreover, *de novo* review denies to litigants the certainty that the *Markman* decision once promised. Indeed, patent cases are about twice as likely as other civil cases to go to trial. About 40% of all claim construction appeals are reversed or vacated. Litigants who might otherwise settle are more willing to risk trial knowing that, whatever happens, they have a good chance of winning on appeal. A standard of review that is more deferential to the trial judge will necessarily lower the reversal rate, force the court to consider the view of skilled artisans, and thus restore certainty and confidence in the patent system.

The BPLA does not advocate overturning *Markman*, allowing juries to construe claims, or any other extraordinary measures. Rather, the BPLA proposes a standard of review like one used in contract cases: when a judge relies on extrinsic evidence to aid claim construction, his or her factual findings — in the words of *Markman*, the "evidentiary underpinnings" of claim construction — should be reviewed for clear error, while the ultimate legal conclusion should be reviewed *de novo*.

ARGUMENT

De novo review for claim construction is not working. First, it is based on the fiction that there is no factual inquiry in claim construction. Second, it deprives litigants of their hefty investment in patent litigation, creates a "zone of uncertainty," and erodes confidence in the patent system.

The case at bar presents an excellent example of this problem. The trial judge expressly relied on expert testimony explaining how skilled artisans would have read the patent. But the Federal Circuit ignored this testimony and the judge's reliance on it. As such, the Federal Circuit did not view the patent through the eyes of one of ordinary skill. Reviewing the claim construction under a deferential standard would have caused the Federal Circuit to consider the expert testimony. Indeed, the dissenter, Circuit Judge Rader, would have deferred to the trial judge and thus would have affirmed.

In *Markman v. Westview Instruments*, 517 U.S. 370 (1996), this Court labeled claim construction a "mongrel practice" with "evidentiary underpinnings." *Id.* at 378, 390. This Court also recognized that "credibility judgments have to be made about the experts who testify in patent cases." *Id.* at 389. While this Court held that this mixed question of law and fact is ultimately for a court alone to decide, it did not specify the standard for reviewing the trial court's decision.

No statute or Supreme Court precedent requires that claim construction must be reviewed purely *de novo*. Just the opposite. This Court's *per curium* decision in *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986), recognizes that when ultimate questions of law (in that case, the question of obviousness) are based on subsidiary findings of fact (such as what the prior art discloses to one of ordinary skill), those subsidiary findings should be reviewed for clear error.

Accordingly, the BPLA urges this Court to review this case, which provides an excellent opportunity to reconsider the Federal Circuit's *de novo* review standard. First, as argued in Section I, claim construction, like the obviousness inquiry, involves subsidiary facts. But *de novo* review allows the Federal Circuit to lose sight of the facts underlying claim construction and thus to depart from how the relevant industry would read a patent. Second, as argued in Section II, *de novo* review causes uncertainty and increases the cost of litigation. Thus, this case presents (a) questions that call for this Court to exercise its supervisory power over the Federal Circuit and (b) important questions of federal law. *See* Supreme Court Rules 10(a) and (c).

I. CLAIM CONSTRUCTION DEPENDS ON FACTS

Invention takes place in the lab. Or in the factory, amidst the hum and clank of machinery. Or even in the weekend inventor's garage workshop, sawdust and oil stains on the floor. Invention involves beakers, soldering irons, lathes, drill presses, calculators, and microscopes. Invention does not take place in a lawyer's office or in the halls of the United States Patent & Trademark Office.

Correspondingly, the primary audience for a patent is the inventor's competitor or fellow artisan — *e.g.*, the white-coated chemist, surrounded by test tubes and Bunsen burners; the machine shop foreman, blueprints spread out before him on the workbench; or even the grease-stained mechanic, wrench and socket in hand. The intended audience is not first and foremost a lay judge or an appellate court:

> Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial

> and treatise for the generalist, instead of a concise statement for persons in the field . . . .

Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 119 (Fed. Cir. 2002). *See also Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 437 (1902) (patent directed to steel-making process was "not addressed to lawyers, or even to the public generally, but to the manufacturers of steel"). Thus, a court will most strongly satisfy the notice function of a patent by defining its scope as it would be understood in the relevant industry. In order to do so, a judge must step out of the courtroom, so to speak, and into the lab or workshop.

The Federal Circuit has likened claim construction to statutory construction. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 987 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). That analogy, however, encourages reference to the real world of invention and technology: "judicial construction ought not to be torn from its wider, non-legal context." Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L. Rev. 527, 528 (1947). Thus, as Justice Frankfurter wrote in the context of statutory construction, "to understand or at least get the feeling of great painting, one does not go to books on the art of painting. One goes to the great masters." *Id.* at 530. Likewise, to understand patented technology, one must go to artisans in the field of invention. Whether a statute or a patent, if it is "addressed to the specialist, [it] must be read by judges with the minds of the specialist." *Id.* at 536.

Patents are typically filled with terms of art — the jargon of the mechanics, engineers, chemists, scientists, and other artisans who form the core audience for patents. But "words of art bring their art with them. They bear the meaning of their habitat whether it be a phrase of technical significance in the scientific or business world." *Id.* at 537. To isolate a

word from its real-world, technological context strips the term of all relevant meaning.

Moreover, many patents involve complex technology beyond the ken of lay people. As the saying goes, "[a]ny sufficiently advanced technology is indistinguishable from magic." Arthur C. Clarke, *Profiles of the Future: An Inquiry into the Limits of the Possible* (1973). Thus, to decipher that magic, judges need experts. Arti K. Rai, *Specialized Trial Courts: Concentrating Expertise on Fact*, 17 Berkeley Tech. L.J. 877, 882 (2002) ("In most cases involving technically complex invention, the judge would be well-advised to turn to the testimony of experts in the relevant scientific or technological community").

Accordingly, litigants present experts, as Merck and Teva did in this case, to help the trial judge understand the technology from the point of view of the skilled artisan. Indeed, statistics show that trial judges admit extrinsic evidence into the claim construction analysis 83% of the time. *See* Cheryl L. Johnson, *The False Premise and Promise of Markman's Decision to Task Judges with Claim Construction and the Judicial Scorecard*, 837 PLI/Pat 9, 61 (2005) (*citing* ABA Section of Intell. Prop. L. 1999, *Markman Survey*, Intell. Prop. L. Newsletter, Spring 2000, at 12). And 80% of those cases admitted expert testimony. *Id.* Finally, 49% of the resulting claim construction rulings in those cases expressly relied on that expert testimony. *Id.*

Thus, in the course of construing claims, trial judges necessarily credit one expert's translation over another's. But judges are well situated to make such credibility determinations:

> It may of course occur that persons experienced in a technologic field will have divergent opinions as to the meaning of a term, particularly as narrow

> distinctions are drawn by the parties or warranted by the technology. Patent disputes often raise close questions requiring refinement of technical definitions in light of particular facts. The judge will then be obliged to decide between contending positions; a role familiar to judges.

Verve, 311 F.3d at 1119–20; *see also Anderson v. City of Bessemer City*, 470 U.S. 564, 574 (1985) (recognizing the trial judge's role and superiority in assessing credibility and determining facts).

Although trial judges rely on expert testimony and other extrinsic evidence in their claim construction opinions, the Federal Circuit has largely ignored this evidence when reviewing claim construction. *See* Eric M. Dobrusin, *Post-Cybor: Can Past Performance Dictate Future Practice?*, IP Litigator, Sept.–Oct. 1998, at 9–10 (1998) (noting that in a study of all claim construction rulings over a certain period, the Federal Circuit mostly confined its review to the intrinsic evidence and rarely considered extrinsic evidence).

This pattern is alarming in two ways. First, it suggests that the Federal Circuit is replacing a specific finding on how one of ordinary skill would read a patent (the correct standard) with its own assumptions on how one of ordinary skill would read the patent. But the judges of the Federal Circuit are neither skilled artisans nor experts on how one of ordinary skill would read patents in every field of invention. Indeed, most Federal Circuit judges do not even have scientific or engineering backgrounds. Kimberly A. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 Lewis & Clark L. Rev. 231, 245 (2005).

Second, it suggests that claim construction today depends more on the unintended meanings of a patent author's word choice than on the actual technology invented. As this Court

recognized, "the nature of language makes it impossible to capture the essence of a thing in a patent application." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). As a result, the "conversion of machine to words allows for unintended idea gaps." *Id.* (citation omitted). But expert testimony explaining how artisans in the relevant industry would understand a given patent helps fill in those idea gaps and thus restores to the patent a better representation of the "machine."

This pattern of ignoring the district court's careful sifting of extrinsic evidence also conflicts with the Federal Circuit's practice in validity disputes. For example, the relevant inquiry for the "anticipation" defense is what the alleged prior art patent or reference discloses to one of ordinary skill in the art. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1349 (Fed. Cir. 2001). The outcome of that inquiry is reviewed with deference to the fact-finder. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002). It is curious, therefore, that the Federal Circuit says in one instance (validity) that what a patent discloses is a question of fact, reviewed with deference, and in the other instance (claim construction), that what a patent discloses is a question of law reviewed *de novo*.

In summary, "facts are often central to the ultimate disposition of patent cases," including to claim construction. Rai, *supra*, at 878. But *de novo* review biases the Federal Circuit away from the underlying facts that help inform the understanding in the art. Accordingly, this *de novo* standard needs reform.

II. *DE NOVO* REVIEW INCREASES UNCERTAINTY AND THE COST OF LITIGATION

In *Markman*, this Court sought in part to shrink the "zone of uncertainty" in the patent system. 517 U.S. at 390 (citing *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938)). When disputes arise over the metes and bounds of patent claims, litigants look to trial judges to construe the disputed claims and reduce uncertainty.

Yet since *Markman*, and particularly since the Federal Circuit solidified its *de novo* standard of review in *Cybor Corp. v. FAS Techs. Inc.*, 138 F.3d 1448 (Fed.Cir. 1998) (en banc), uncertainty as increased. In particular, the reversal rate has actually increased since the *Cybor* ruling, contrary to Markman's intent. Kimberly A. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 Lewis & Clark L. Rev. 231, 246–47 (2005).

De novo review of claim construction makes district court rulings little more than costly (and often temporary) "first takes" at claim construction. Various studies have shown that the Federal Circuit's reversal rate for claim construction rulings is at least 30% to 40%, depending on the statistical method used. *See, e.g., See* Cheryl L. Johnson, *The False Premise and Promise of Markman's Decision to Task Judges with Claim Construction and the Judicial Scorecard*, 837 PLI/Pat 9, 64–66 (2005) (summarizing various empirical studies showing the reversal rate hovers near 40%); Christian A. Chu, *Empirical Analysis of the Federal Circuit's Claim Construction Trends*, 16 Berkeley Tech. L.J. 1075, 1104 (2001) (claim construction modified in 44% of cases in the study); Moore, *Eight Years Later*, *supra*, at 233 (finding that the Federal Circuit reversed 34.5% of the claims construction cases between 1996 and 2003).

These reversal rates are the highest by far in the federal court system. In comparison, only about 8% of all civil appeals are reversed. *See* Admin. Office of the U.S. Courts, *U.S. Courts of Appeals—Appeals Terminated on the Merits, By Circuit, During the 12-Month Period Ending December 31, 2004* 1 (2005). Some might interpret this contrast to suggest that trial judges do not understand patents — that they are not listening to the Federal Circuit, following its canons of claim construction, or seeing enough patent cases to gain experience in claim construction.

The BPLA, however, observes that trial judges do understand patents, work hard at doing so, and, importantly, understand when to defer to the expertise of those of ordinary skill in translating patented technology. Indeed, statistics show that a significant number of all patent cases arise in just ten district courts. Arti K. Rai, *Specialized Trial Courts: Concentrating Expertise on Fact*, 17 Berkeley Tech. L.J. 877, 880 (2002) (*citing* Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation*?, 79 N.C. L. Rev. 889 (2000)). This statistic suggests that the judges in these courts see enough cases to gain experience and thus facility with patents.

De novo review of claim construction does nothing to promote certainty among property owners or to diminish disputes. Early settlements become less likely when litigants know that an adverse claim construction in the trial court can be argued anew to the Federal Circuit. As such, *de novo* review creates little incentive to settle before trial. Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 Harv. J.L. & Tech. 1, 27-28 (2001); Johnson, *supra*, at 18. Not surprisingly, patent disputes go to trial at nearly twice the rate of general civil litigation. James Bessen & Michael J. Meurer, *Lessons For Patent Policy From Empirical Research On Patent Litigation*, 9 Lewis & Clark L. Rev. 1, 3 (2005) (citation omitted).

Correspondingly, litigation costs have skyrocketed because the prospect of *de novo* review and reversal prolongs litigation and compounds expenses. The Federal Circuit's high reversal rate is a strong incentive to litigate patent claims to judgment and appeal after receiving an early adverse claim construction ruling. Moore, *District Court Judges*, *supra*, at 27–28. Studies estimate that the median cost of patent litigation is about $2 to 4 million, depending on the amount of damages at risk. Bessen & Meurer, *supra*, at 2 (*citing* Am. Intellectual Prop. Law Assoc., *Report of the Economic Survey 2003* (2003)).

In sum, *de novo* review of claim construction rulings discourages settlement, prolongs litigation, and compounds expenses. The ability of the patent system to promote certainty among property owners and diminish disputes has been weakened by the lack of deference to the trial courts.

III. A PROPOSED STANDARD OF REVIEW AND ITS APPLICATION TO THIS CASE

The BPLA proposes a standard of review that defers to the "evidentiary underpinnings" of claim construction. In particular, this Court has analogized claim construction to judicial exegesis of other written instruments, such as contracts. *Markman*, 517 U.S. at 381–2. The Federal Circuit holds that when trial courts receive evidence to resolve interpretation of contract terms, the Federal Circuit reviews the resulting findings of fact for clear error and reviews *de novo* the ultimate contract interpretation based on those facts. *C. Sanchez & Son, Inc. v. United States*, 6 F.3d 1539, 1544 (Fed. Cir. 1993).

Likewise, by analogy to contract cases, the Federal Circuit should review any factual findings underlying a trial judge's claim construction for clear error — particularly as to how one of ordinary skill would read the patent.

In this case, the trial judge found that, on cross-examination, Teva's own expert, Dr. Russell, admitted that one of ordinary skill would have read the patent as Merck proposes. The trial judge found that Dr. Russell "testified that Merck's proffered construction is the definition as it is described in the patent." *See* Merck's Appendix at 64a. This fact played an important role in the trial judge's construction of the disputed claims.

The Federal Circuit's opinion, however, nowhere mentions this testimony. Had the Federal Circuit deferred to this finding, it would have at least considered the point of view of one skilled in the art. The Federal Circuit thus would have avoided the battle of semantics over the word "about" and would have gotten closer to the machine, so to speak—closer to the methods and compositions claimed in Merck's patent.

CONCLUSION

The Boston Patent Law Association urges this Court to grant a writ of *certiorari* and to modify the Federal Circuit's *de novo* standard of review of claim construction rulings.

Respectfully submitted,

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